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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Defendant Meridian Bioscience, Inc.
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Submission	Testimony For Defendant
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

	) Opposition No. 91194218
ILLUMINA, INC.,	) (parent)
	) Serial No. 77/768176
Opposer/Petitioner,	) Opposition No. 91194219
	) Serial No. 77/775316
vs.	)
	)
MERIDIAN BIOSCIENCE, INC.,	) Cancellation No.
	) 92053479 Reg. No. 3887164
Applicant/Registrant.	) Cancellation No.
	) 92053479 Reg. No. 386801

CONFIDENTIAL - PURSUANT TO THE PROTECTIVE ORDER

Tuesday, May 12, 2015

DEPOSITION OF NAOMI O'GRADY, a witness herein, called by the Applicant/Registrant, Meridian Bioscience, Inc., at 12790 El Camino Real, San Diego, California, commencing 8:29 a.m. and concluding 5:25 p.m., before Karla Meyer Baez, RPR-CRR, CSR No. 4506, Certified Shorthand Reporter in and for the State of California.

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A P P E A R A N C E S

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EXHIBITS

EXHIBITS (CONTINUED)

EXHIBITS (CONTINUED)

SAN DIEGO, CALIFORNIA

TUESDAY, MAY 12, 2015; 8:29 A.M.

NAOMI O'GRADY

having been first duly sworn by the Certified Shorthand Reporter, was examined and testified as follows:

EXAMINATION

BY MR. HANKINSON:

Q. Good morning.

A. Good morning.

Q. I'm Tom Hankinson. I'm here on behalf of Meridian Bioscience.

Do other people want to state their presence?

MR. HORNE: Sure. Brian Horne from Knobbe for Illumina. Will Noon from Illumina is with me.

BY MR. HANKINSON:

Q. Could you state your name and spell your last name.

A. Sure. Naomi O'Grady, O apostrophe G-R-A-D-Y.

Q. You've given a deposition previously in this case; right?

A. Yes.

Q. Last December?

A. I don't recall the exact date, but yes, around that time frame.

Q. The same guidelines and ground rules are going to apply today. Do you have a good recollection of those, or maybe I should go over them again?

A. I wouldn't mind if you went over them again.

Q. Sure. The court reporter is here. She is going to be taking down everything that we say. So it helps if I complete my question. Maybe there will be an opportunity for Mr. Horne to object. If he doesn't and there is a pause, then you can answer. If he does, let him finish and then you can answer, and I'll try to wait until you're complete with your answer until I speak again, and that way it all gets taken down.

Is that okay?

A. Yes.

Q. And you do a very good job with this, but answer out loud and in words, because nods don't get taken down and "uh-huhs" or "huh-huhs" can be ambiguous in writing.

So do you mind answering "yes" or "no" or

otherwise in words?

A. Yes. That's fine.

MR. HORNE: Good job.

BY MR. HANKINSON:

Q. If you want to take a break, you can at any time, but you'll have to answer the question that's pending and then ask for a break, and then we can do that.

A. Okay.

Q. If you answer my question, then I'm going to assume that you understand it. If you don't understand it, please ask me to either repeat it, if that's what you need, or rephrase it.

Will you do that?

A. Yes.

Q. For what years did you attend undergraduate school?

A. I graduated in 2007, and I think it took two and a half years. I don't recall exactly, but I think it was 2005 and 2007.

Q. Did you work prior to going to undergraduate school?

A. Yes.
Q. What kind of job?
A. I was working at a biotech company called Nanogen. I held a variety of positions there.
Q. Straight out of high school?
A. No. After I graduated.
Q. You were talking about graduate school?
A. I didn't answer your question correctly. I'm sorry.
Q. No problem.
A. I was talking about graduate school.
Q. Got it. So you spent approximately two and a half years in business school?
A. In business school, yes.
Q. Maybe from 2005. And in any event you graduated from business school in 2007?
A. That's right.
Q. When did you attend undergraduate school?
A. Approximately '96 to 2000, give or take a year.
Q. Did you graduate in 2000?
A. I can't recall if it was 2000 or 2001.
Q. You don't have your class ring to check?

A. No.

Q. So you spent about five years in undergraduate school?

A. Yes.

Q. And if I'm remembering, you got a bachelor of science degree?

A. Yes.

Q. In microbiology?

A. Biology.

Q. Biology. And after you graduated you -- from undergraduate university you began working for Nanogen?

A. Yes.

Q. And you worked there in various capacities up to and including your time in business school?

A. Yes.

Q. What was the highest position that you held at Nanogen?

A. Product manager.

Q. Was that in a marketing capacity?

A. Yes.

Q. In what year did you leave Nanogen?

A. 2007.

Q. Around the same time that you graduated business school?

A. Yes.

Q. Was your next job at Illumina?

A. Yes.

Q. And did that begin in 2007?

A. Yes.

Q. Did your knowledge of Illumina and its products come from your time working there?

MR. HORNE: Vague.

A. Can you rephrase the question.

BY MR. HANKINSON:

Q. Were you a fan of Illumina with posters on the wall in high school?

A. No.

Q. Did you learn about Illumina and its products when you came to work for Illumina?

A. I knew of Illumina before I started there.

Q. Just that the company existed and that it was a large biotechnology company?

A. I was attracted to them because of their reputation.

Q. When did you first hear about them?
A. 2005 or '-6.
Q. During business school?
A. During business school and also in the course of business at Nanogen. I'm sorry. Yeah, Nanogen.
Q. Do you hold any postgraduate degrees in a scientific field?
A. No.
Q. Have you been employed within a research laboratory?
A. I --
MR. HORNE: Vague.
A. I don't understand what you mean by a research laboratory.
BY MR. HANKINSON:
Q. So you've been employed within a laboratory?
A. Yes.
Q. What was that laboratory?
A. I was employed at Children's Hospital in their cytogenetics laboratory.
Q. When?
A. I don't remember the exact years, but while I

was an undergraduate for the last two years and including some time after graduation.

Q. Do you hold any certifications in a scientific field?

A. I hold a certification in product development under design control.

Q. Which is a regulatory field?

A. Yes.

Q. So do you hold any certifications in a scientific field?

A. No.

Q. Have the jobs that you have mentioned so far encompassed all of your work experience?

MR. HORNE: Vague.

A. No.

BY MR. HANKINSON:

Q. And where else have you worked?

A. The -- including Nanogen, Illumina, and the cytogenetics lab, those represent my experience in the biotech field.

Prior to that I held various jobs in order to sustain myself through college.

Q. You wouldn't consider them part of your professional career?

A. No.

MR. HANKINSON: Let's mark this as Exhibit M.

(O'Grady Exhibit M was marked for identification)

BY MR. HANKINSON:

Q. Is Exhibit M a copy of your rebuttal declaration in this matter?

A. Yes.

Q. Did you sign the declaration that is Exhibit M on April 8th, 2015?

A. Yes.

Q. Generally is one of the points that you attempt to make in this rebuttal declaration that Illumina has had a long-standing presence in the molecular diagnostics field?

MR. HORNE: Vague.

A. I don't know.

BY MR. HANKINSON:

Q. So this declaration does not attempt to show that Illumina has a long-standing presence in the

molecular diagnostic field?

MR. HORNE: Vague, mischaracterizes testimony.

A. I don't know if I would say that it's a summary statement of the deposition -- or declaration.

BY MR. HANKINSON:

Q. So if one reads this declaration, it does not show that Illumina has had a long-standing presence in the diagnostics field?

MR. HORNE: Vague, mischaracterizes testimony.

A. I don't know.

MR. HORNE: Lacks foundation.

BY MR. HANKINSON:

Q. You wrote this declaration; right?

A. Yes.

Q. And you signed it?

A. Yes.

Q. You had some purpose for doing so?

A. Yes.

Q. And the purpose was to aid your company in this case; right?

A. Yes.

Q. And paragraph one says "I have personal

knowledge of the matters set forth herein, and if called upon to testify I could and would competently testified thereto"; right?

A. Yes.

Q. Do you believe that to be true?

A. Yes.

Q. A lot of the statements in this declaration have to do with laboratory-developed tests; right?

MR. HORNE: Vague.

A. Some of them do.

BY MR. HANKINSON:

Q. But not a lot?

MR. HORNE: Vague.

A. I'm sorry, I don't understand what you're saying.

BY MR. HANKINSON:

Q. Well, I asked you if a lot of them did, and you said some of them do. So not a lot, just some.

MR. HORNE: Vague, argumentative.

A. I don't -- I don't understand what you're asking me.

/////////

BY MR. HANKINSON:

Q. Well, I asked if a lot of the statements in this declaration have to do with laboratory-developed tests.

Do you remember that question?

MR. HORNE: Vague, argumentative.

A. Yes.

BY MR. HANKINSON:

Q. And instead of saying "yes" to answer that a lot of them do, you said "some of them do"; right?

A. Yes.

Q. And so you quibbled with the word "a lot," and you were more comfortable saying that "some of them do." Is that a fair statement?

MR. HORNE: Vague, argumentative, mischaracterizes testimony.

A. I haven't precisely characterized the quantity of statements that relate to the LDTs in this document.

BY MR. HANKINSON:

Q. So in this document do you often reference laboratory-developed tests?

MR. HORNE: Vague.

A. I reference laboratory-developed tests in the declaration.

BY MR. HANKINSON:

Q. So you would agree with your attorney that the term "often" is vague?

A. Yes.

Q. And unless you counted how many statements there are total in the declaration and then counted how many statements referenced laboratory-developed tests, you won't know the percentage that reference laboratory-developed tests; right?

A. Yes.

Q. And if instead you just said that a lot of them have to do with laboratory-developed tests or that it often references laboratory-developed tests, those would be vague terms without the numbers to back them; right?

MR. HORNE: Argumentative, vague.

A. Yes.

BY MR. HANKINSON:

Q. Could you turn to paragraph 15. In paragraph 15 you say, "In fact, LDTs are commonly used to diagnose patients. Often the same clinicians in a lab are using

both LDTs and IVDs."

Do you see those two paragraphs in Exhibit 15?

A. Yes.

Q. That's in Exhibit M, your declaration; right?

A. Yes.

Q. You don't present a percentage of how many clinicians in a lab are using both LDTs and IVDs, do you?

A. No.

Q. So your phrase "often" is vague; correct?

MR. HORNE: Argumentative.

BY MR. HANKINSON:

Q. Otherwise you're just saying it's okay for you to use it when you want to, but it's vague when I'm asking a question that uses the term. So is that vague or not?

MR. HORNE: Argumentative, mischaracterizes her testimony, and your question is vague.

BY MR. HANKINSON:

Q. Let me ask a new question.

Did you present in this declaration, Exhibit M, a total number of laboratories?

A. No.
Q. Did you count how many clinicians within labs use both LDTs and IVDs in this declaration?
A. No.
Q. And yet you offer the opinion that often the same clinicians in a lab are using both LDTs and IVDs; right?
A. Yes.
Q. And here today you've agreed that if you use the word "often" to describe something without counting the total and counting the number of hits, that that's a vague term; right?
MR. HORNE: Argumentative, vague, mischaracterizes her testimony.
A. I'm sorry, what are you asking me?
BY MR. HANKINSON:
Q. Are you uncomfortable with the question?
A. I don't understand what you're asking me.
MR. HANKINSON: Could you read it back, please. I'm sorry if it's an imposition. I hope that's okay.
(Question was read)
A. It's not quantitative. It's not quantitative.

BY MR. HANKINSON:

Q. And earlier you agreed that the term "often" is vague when your attorney objected that my use was vague; right?

MR. HORNE: Mischaracterizes testimony.

Go ahead.

A. Yes, I agree.

BY MR. HANKINSON:

Q. Would your answers to the series of questions that I just asked about the word "often" apply to each time that you characterize something as happening often within your declaration that is Exhibit M?

A. I don't know.

Q. "Often" might mean different things to you at different times in your declaration so that you would answer those questions differently?

A. I don't have an opinion of what it meant every single time I said it sitting here right now to answer that question.

Q. Paragraph 1, that says that you have personal knowledge of the matters set forth herein and if called upon to testify you could and would competently testify

thereto; right?

A. Yes.

Q. So that means that you are the person who is going to testify today about this declaration; there is not someone else; right?

A. No. That's right.

Q. And these are your words?

A. Yes.

Q. And I'm asking you about your use of the word "often," which you've said is vague; right?

A. Yes.

MR. HORNE: Mischaracterizes --

BY MR. HANKINSON:

Q. I'm just asking you if that applies each time you use the word "often."

MR. HORNE: Compound. You want to go through each term one by one?

MR. HANKINSON: Mr. Horne stated an objection.

MR. HORNE: It's a question to you.

THE WITNESS: Is there a question for me to answer?

///////

BY MR. HANKINSON:

Q. Yes.

A. Would you please restate it.

MR. HANKINSON: Would you mind reading it back, please.

(Question was read)

MR. HORNE: The question is whether you wanted to go through each term or not.

A. I do not believe -- I do not believe every time I used the word "often" is vague.

BY MR. HANKINSON:

Q. Do you understand that this case will be decided by a Trademark Trial and Appeal Board?

A. No.

Q. Do you understand that someone will decide this case?

A. Yes.

Q. Do you understand that your rebuttal declaration, in addition to other evidence in the case, will be submitted to that person or group of people in order to decide the case?

A. Yes.

Q. So you understand that someone will be reading your declaration and then trying to make conclusions that matter in this case based on it; right?

A. Yes.

Q. And you are telling that person that when you use the word "often" in your declaration it is sometimes vague but sometimes may not be vague; is that accurate?

MR. HORNE: Mischaracterizes testimony, argumentative.

A. Are you asking me if I understand that?

BY MR. HANKINSON:

Q. Yes.

A. I understand what you're saying to me.

Q. And you understand that it is true about the world [verbatim]?

A. I don't understand what you just said.

Q. Well, you said you understand the words coming out of my mouth, right? That was what your answer was intended to convey. And I'm asking you if you understand that that concept that I just described is true, it's a true thing.

A. Can I try to restate what I think you're saying

to me because I --

Q. No. I'd --

A. The trail of conversation is hard for me to follow.

MR. HORNE: Then ask for the question to be repeated if you can't remember what the question on the table is.

A. Can you please restate your question to me?

BY MR. HANKINSON:

Q. Do you understand -- pardon me. Let me start again.

You are, in testifying here today, telling the person who will decide this case that when you use the word "often" in Exhibit M, your rebuttal declaration, it sometimes is vague, but other times it may not be vague; is that correct?

MR. HORNE: Argumentative, mischaracterizes the testimony, and the question is vague.

A. I do not believe that my statements are vague.

BY MR. HANKINSON:

Q. You agree that one use of the term "often" was vague, right, when there weren't numbers to back it up?

MR. HORNE: Vague, mischaracterizes testimony, argumentative.

A. I --

BY MR. HANKINSON:

Q. Are you looking at paragraph 15?

A. Yes, I am. Though the statement in paragraph 15 says "Often the same clinicians in the lab are using both LDTs and IVDs," which I believe to be true.

And I explain why by saying it's because the rapidly evolving needs of the diagnostic level outpace the process of becoming an IVD are approved -- I'm sorry -- an FDA cleared or approved IVD. I don't believe that that is vague. It's true.

Q. So when you told me before that that use of the word "often," just like my use of the word "often" was vague, you weren't being completely honest with me?

A. I don't -- I didn't understand.

MR. HORNE: Argumentative.

A. I didn't understand what you're asking me.

MR. HORNE: Mischaracterizes testimony.

BY MR. HANKINSON:

Q. We were talking how about in order to

characterize something as "often" and not be vague, you would have to count the total and then count the number of times in which that thing were true and determine a percentage.

Do you remember when we discussed that?

MR. HORNE: Mischaracterizes her testimony, argumentative.

Go ahead.

A. I remember when we discussed that.

BY MR. HANKINSON:

Q. And do you remember agreeing with that premise?

MR. HORNE: Argumentative, mischaracterizes testimony.

A. I believe the word "often" alone may be vague. In the context of a sentence or a paragraph it may not be. It depends on the context of the conversation.

BY MR. HANKINSON:

Q. And you are telling the person or people who will decide this case that the word "often" may or may not be vague depending on the context when they read your declaration; right?

MR. HORNE: Mischaracterizes testimony,

argumentative.
BY MR. HANKINSON:
Q. I'm just saying what you said, but I'm saying you're telling it to the Trademark Trial and Appeal Board. So you agree with that; right?
MR. HORNE: Argumentative, mischaracterizes testimony.
BY MR. HANKINSON:
Q. Please answer the question. Is it different for you sitting here than it is when the Trademark Trial and Appeal Board is deciding the case? Is the answer changed somehow?
A. No.
Q. Okay. So it's the same; right?
MR. HORNE: Argumentative.
A. The word "often" may or may not be vague in the context of a conversation based on the information provided. I do not agree that you can take that word and say it's vague completely without looking at the context.
BY MR. HANKINSON:
Q. And if the context does not provide a total

number of things and then a number of things that are hits, that are times when the thing you're talking about happened, that it's a vague concept; it doesn't have a percentage behind it?

MR. HORNE: Argumentative.

A. I do not believe that's the only way to provide context to the word "often."

BY MR. HANKINSON:

Q. Do you agree that there are no numbers in paragraph 15? That's pretty straightforward.

A. Yes, I agree.

MR. HANKINSON: Can we mark this as Exhibit N.

(O'Grady Exhibit N was marked for identification)

BY MR. HANKINSON:

Q. Exhibit N is your company's responses and objections to Meridian's Second Set of Interrogatories. Do you see that, the title?

A. Yes.

Q. And you understand that this information was provided to Meridian in the course of this matter by your company?

A. Yes.

Q. Could you look at page 3 and specifically interrogatory number 44. Do you see that on page 3 of Exhibit N?

A. Yes.

Q. Interrogatory 44 asks, "Identify the date on which Opposer first sold or offered for sale, whichever is earlier, products or services under the Illumina Marks that could be used in a clinical diagnostics lab of a hospital or reference laboratory."

Do you see interrogatory 44 where it says that?

A. Yes.

Q. In response, your company, Illumina, noted here as Opposer, stated "Opposer incorporates its general objections and its objections to definitions as if fully set forth herein."

"Opposer objects to this interrogatory as vague in that it is not clear what is meant by 'could be used.'"

Do you see that?

A. Yes.

Q. Do you agree with your company's attorneys that

the phrase "could be used" is vague when applied to whether products or services under the Illumina Marks could be used in a clinical diagnostics lab of a hospital or a reference laboratory?

MR. HORNE: Argumentative, mischaracterizes the document.

A. I'm sorry, can I hear the end of that question again, please.

BY MR. HANKINSON:

Q. Yes.

Would you mind reading it.

(Question was read.)

MR. HORNE: Same objections.

A. The term "could be used" in a clinical diagnostics lab or hospital or reference laboratory means something to me. I don't understand why it's considered vague.

BY MR. HANKINSON:

Q. So you disagree with your company's attorneys on that?

MR. HORNE: Argumentative, lacks foundation, mischaracterizes the testimony and the document.

A. I don't understand why that would be vague.
BY MR. HANKINSON:
Q. And this occurred, this statement from your company's attorneys, when Meridian was asking a question about when Illumina-branded products could be used in such a setting; and that was their response, that "could be used" is vague. You understand that; right?
MR. HORNE: Argumentative, mischaracterizes the document.
BY MR. HANKINSON:
Q. That was the context in which this appeared; right?
MR. HORNE: Same objections.
BY MR. HANKINSON:
Q. Was Meridian the company that was using the phrase "could be used" in its interrogatory?
A. I don't know the answer to that question.
Q. You understand that these are interrogatories that were asked by Meridian. You said that earlier; right?
A. Yes.
Q. You see interrogatory number 44 --

A. Yes.

Q. -- right? You see the phrase "could be used" in that interrogatory; right?

A. Yes.

Q. And so the objection by your company's attorneys was to Meridian --

A. Okay.

Q. -- using the term "could be used" as it applies to Illumina-branded products in such a setting; right? You understand that?

MR. HORNE: Argumentative, mischaracterizes the document.

A. Yes. I see what this says, and I understand now that the interrogatory number 44 is what Meridian said and the response is what Illumina said.

BY MR. HANKINSON:

Q. And now you are saying that when you, Miss O'Grady, use the term "could be used" or "can be used" in the rebuttal declaration that is Exhibit M it's somehow not vague anymore. Is that what you're saying?

MR. HORNE: Argumentative, mischaracterizes the document and her testimony.

A. I did not say it was vague. I said it means something to me.

BY MR. HANKINSON:

Q. And so when you use the term "could be used" or "can be used" in your rebuttal declaration, you're saying that it means something that is not vague; right?

A. Yes.

Q. And that's the opposite of what Illumina's attorneys said when Meridian used that term; right?

MR. HORNE: Argumentative, lacks foundation, and -- sorry, mischaracterizes the document.

A. I don't know the full context of how the phrase "could be used" was discussed with Meridian.

BY MR. HANKINSON:

Q. Well, do you offer opinions in your rebuttal declaration that is Exhibit M about Illumina-branded products that could be used or can be used in a clinical diagnostics setting?

MR. HORNE: Vague.

A. I don't believe that they are opinions. Products can be used in a clinical laboratory. It's possible.

BY MR. HANKINSON:

Q. So you don't offer an opinion on that in your rebuttal declaration?

MR. HORNE: Vague.

A. I'm saying that it is true that our products can be used in a clinical laboratory.

BY MR. HANKINSON:

Q. And you're saying it's not an opinion.

A. I don't --

MR. HORNE: Vague.

A. It is technically possible for a laboratory to use our products in a clinical setting. It's not an opinion.

BY MR. HANKINSON:

Q. Oh, so you're not offering an opinion in your rebuttal declaration that would help someone determine from an expert standpoint whether Illumina-branded products can be used or could be used in a clinical diagnostics setting. Rather, you're saying it is technically possible to use them as such as a matter of fact. Do I have that right?

MR. HORNE: Vague, argumentative.

A. I don't -- I'm -- I don't agree with applying in a general sense what I just said to the entire document. There --

BY MR. HANKINSON:

Q. So when you use the word "can be used" or "could be used," those words, they mean different things in different contexts?

MR. HORNE: Argumentative, mischaracterizes testimony.

A. I'm not comfortable generalizing every single instance of the phrase of that term, sitting here and not looking at it.

BY MR. HANKINSON:

Q. Let's go to paragraph 2 of your declaration. There you disagree with Ken Kozak of Meridian Bioscience; right?

A. Yes.

Q. And in paragraph 3 you say, "Illumina's customers are not limited to research labs"; right?

A. Yes.

Q. Instead, since at least 2007 you say Illumina's products have been used in clinical diagnostic labs;

right?

A. Yes.

Q. And you are referring in paragraph 3 to use as part of laboratory-developed tests; right?

MR. HORNE: Vague.

A. Not exclusively.

BY MR. HANKINSON:

Q. Oh, was there one that was used in a clinical diagnostics laboratory since at least 2007 that was not part of a laboratory-developed test at that time?

MR. HORNE: Vague.

BY MR. HANKINSON:

Q. You certainly don't make that assertion elsewhere in your declaration?

MR. HORNE: Argumentative, mischaracterizes the declaration, and vague.

A. From 2007 until today, there are examples of products being used in a clinical diagnostics lab that are IVDs as well as LDTs at various times along that time frame.

BY MR. HANKINSON:

Q. Right. So this is an ambiguous phrase, isn't

it?

MR. HORNE: Argumentative.

A. I do not agree.

BY MR. HANKINSON:

Q. Well, there are certain times when an Illumina-branded product was only used in a clinical diagnostics setting as part of a laboratory-developed test, and then there are other times since 2007 after which Illumina-branded products had clearance from FDA; right?

A. Yes.

Q. And those are two distinct ideas; right?

MR. HORNE: Vague. Argumentative.

A. The -- an LDT and an IVD are distinct in the label on the product, and by "label" I mean the intended use, and -- but the clinical diagnostics lab and the service they offer both qualify as diagnostics.

BY MR. HANKINSON:

Q. And that's the distinction; right?

A. Yes.

Q. And the labeling has to do with the regulations that apply; right?

A. That's right.

Q. And so a research use only labeled product cannot be marketed and sold for the purpose of being used in clinical diagnostics. Do I have that correct?

A. Yes.

Q. Nevertheless, it is your contention in your rebuttal declaration that there were RUO products, that although they were not marketed and sold to be used in clinical diagnostics, were so used under the discretion of a lab. Do I have that right?

A. When you say marketed and sold, in order for a customer to buy a product they have to be sold.

Q. I'll ask a different question.

A. Okay.

Q. Between 2007 and the end of 2009, the products that you say were Illumina's products in paragraph 3 that have been used in clinical diagnostics labs were labeled for research use only; correct?

A. Yes.

Q. And those products were used in clinical diagnostics labs, to the extent that they were, at the discretion of the lab. They were not marketed to be

used as clinical diagnostics tools. Do I have that correct?

A. Yes.

Q. From that premise the selection of Illumina's RUO-labeled products to be used in clinical diagnostics, you argue in your rebuttal declaration that even though Illumina had no IVD products cleared by the FDA, it nevertheless had some products in labs that did do clinical diagnostics. That's the premise of your argument; right?

MR. HORNE: The question is argumentative.

A. Can I -- I apologize. Can I hear the question again.

MR. HANKINSON: Uh-huh. If you would be so kind.

(Question was read)

A. Yes.

BY MR. HANKINSON:

Q. And you argue from that premise that there was awareness in the clinical diagnostics market of Illumina's branded products, even though none had been FDA cleared at that time; right?

A. Yes.

MR. HORNE: Argumentative.

BY MR. HANKINSON:

Q. And so your contention in this rebuttal declaration is that Illumina has had awareness of its brand in clinical diagnostics labs since 2007 because of that?

A. Yes.

Q. And so that's now been about eight years that Illumina has had some presence in the minds of customers in clinical diagnostics labs, according to you; right?

A. Yes.

Q. And over the course of that eight years you also argue in your rebuttal declaration that Meridian came later with its IVD-cleared Illumigene product; right?

Let me ask a different question. I don't want to get tied up on that.

A. Okay.

Q. You also argue in your rebuttal declaration that Illumina sent marketing materials to employees of laboratories that did clinical diagnostics work because

they were part of an email list that included employees of labs that did clinical diagnostics work and employees of labs that did only research and employees of labs that did a mix, because Illumina had purchased these email lists and the laboratory employees were not divvied up between those three buckets. It was a list, and Illumina sent its marketing materials to the whole list. Do I have that right?

MR. HORNE: Argumentative, mischaracterizes the document.

A. I don't -- No.

BY MR. HANKINSON:

Q. You know the list that I'm talking about --

A. Yes.

Q. -- the email list?

A. Uh-huh.

Q. And actually you say that Illumina used one or more of -- a group of email lists in your declaration?

A. Yes.

Q. But you don't say which one?

A. No.

Q. In your declaration you identify two possible

lists; right?

MR. HORNE: Mischaracterizes the document.

A. Can you show me where you're saying I --

BY MR. HANKINSON:

Q. You're looking at paragraph 9; right?

A. Yes.

Q. Illumina rents customer lists from one or more of the aforementioned associations.

Do you see that?

A. Yes.

Q. Okay. Aforementioned associations, Association of Molecular Pathology and College of American Pathologists in paragraph 8. Right?

A. Yes.

Q. So there is two?

A. You're asking me if I point out two in this document?

Q. You point out two possible sources of this email list.

A. Yes.

Q. And then you said one or more of them were used by Illumina?

A. Yes.

Q. And getting back to my question, the list that Illumina rented happened to include employees of laboratories that just did research and employees of laboratories that did clinical diagnostics, employees of laboratories that did both, and they weren't differentiated on the email list. Is that what you're saying?

A. No.

Q. So they were differentiated?

A. My disagreement is not about the separation about research and clinical use. My disagreement is about the differentiation of infectious disease and genetic testing.

Q. I didn't ask any questions about that.

A. I -- I'm -- the differentiation that you're stating is not true.

Q. So the email list is differentiated between employees of labs that do only research, employees of labs that do clinical diagnostics, and employees of laboratories that may do both?

MR. HORNE: Mischaracterizes the document or

declaration.

A. I don't know.

BY MR. HANKINSON:

Q. Did you have any responsibility for sending out the emails?

A. I was involved in it, yes.

Q. And you don't know?

A. The options for inclusion did not segregate in the way that you described it between research or clinical or somewhere in between. It was not segregated in that way. It was not an option.

Q. So why didn't you just tell me that.

A. Because I didn't understand what you were asking me.

Q. There is no distinction made on that email list between those three categories?

A. No.

Q. The answer is "yes"?

A. I'm sorry?

MR. HORNE: Vague.

A. There is no distinction in the email list between research and clinical.

BY MR. HANKINSON:

Q. And that's why Illumina's marketing materials went to a group of laboratory employees that included some who did clinical diagnostics?

A. No.

Q. So Illumina was purposely sending emails to employees of laboratories that did clinical diagnostics; that's what you contend?

A. Yes.

Q. And that was to put a presence in their mind of Illumina as a brand. That's your contention; right?

A. Yes.

Q. And you are arguing in this rebuttal declaration that that was successful in that the market of the clinical diagnostics field had awareness of Illumina's brand and products, even prior to the clearance of IVD products by the FDA.

Is that your contention?

A. Yes.

Q. And that had been going on for many years as well. We talked about eight years before. This email list thing had been going on for how many years? You

don't say in your declaration, but how many?

A. I don't know.

Q. So this could have been instituted at some different time than 2007?

A. We marketed at the Association for Molecular Pathology in 2011 -- I'm sorry -- 2007 and --

Q. You're referring to a trade show?

A. A trade show or a conference.

Q. Could you please answer my question as to the emails.

MR. HORNE: I think she's trying.

MR. HANKINSON: No, she's not.

MR. HORNE: She is. Let her answer.

A. Exhibiting at those shows includes an email to the participants in the meeting or a direct mail, and we participated in that.

BY MR. HANKINSON:

Q. Do you -- Is that the same thing as these email lists that we're talking about?

A. It is an example of.

Q. Is it an example that you identified in your declaration?

A. Not specifically.

Q. Right, because Illumina didn't send the email that you're talking about; right?

MR. HORNE: Argumentative, lacks foundation.

A. I don't understand.

BY MR. HANKINSON:

Q. The email that goes along with the trade show participation, Illumina doesn't send that email, does it? You're talking about an email sent by the organization that's putting on the trade show; right?

A. So as part of a participation in a trade show, a -- including AMP and CAP, a direct mail is sent by Illumina from a mail house. The list of participants is provided by the conference provider.

Q. Mail or email?

A. Hard mail.

Q. Okay. So I was asking you about an email list. Right?

A. Uh-huh.

Q. And you did not answer my question.

A. Okay. I'm sorry. Can you state it again.

Q. Okay. When did Illumina's use --

A. Uh-huh.
Q. -- of the email marketing that you describe in your rebuttal declaration --
A. Yes.
Q. -- begin?
MR. HORNE: Argumentative, mischaracterizes the declaration.
A. I don't know the exact origin of our first email campaign. I don't know the first email campaign, when that happened.
BY MR. HANKINSON:
Q. What is the first email campaign of Illumina that was sent to a list that included employees of laboratories that may have done clinical diagnostics, that you were aware of?
MR. HORNE: Talking about email?
A. Email?
BY MR. HANKINSON:
Q. I'm talking about the question I asked.
A. So I was involved with email for a campaign -- I don't remember the exact date. I'm sorry.
Q. It's not in your declaration; right?

A. No.

Q. In your rebuttal declaration when are you saying that employees of laboratories that may have done clinical diagnostics were aware of Illumina's branded products? What point in time?

MR. HORNE: Vague.

A. We're saying that -- I'm saying that in 2007 Illumina was building awareness of our products in a clinical lab setting.

BY MR. HANKINSON:

Q. When was that awareness built?

MR. HORNE: Vague.

BY MR. HANKINSON:

Q. I agree it's vague, actually. What are you talking about?

A. I --

MR. HORNE: Vague.

A. I'm trying to answer your question.

BY MR. HORNE:

Q. In 2007 Illumina was building a presence in the clinical diagnostics market, is what your answer was; and then I said, "well, when was that presence built";

and you said "I don't understand," and your counsel objected that it was vague.

So what are you talking about?

MR. HORNE: If you can understand that question.

A. We -- Illumina exhibited at the Association for Molecular Pathology in 2007 with the BeadXpress Reader. That was my first participation in that meeting with Illumina. I -- No, I was not with Illumina at that time. I started just -- No, I'm sorry.

Association for Molecular Pathology usually happens in the fall, in November; and I started at Illumina in October, and I -- my first participation in that meeting with Illumina was in 2007 where we exhibited the BeadXpress.

MR. HORNE: Take a break in a minute?

MR. HANKINSON: Sure.

Q. And so I asked when the awareness in customers within labs that may do clinical diagnostics had been built, and you said your first participation in a CAP meeting with Illumina was in November of 2007. Is that an answer to my question?

A. I said AMP, Association of Molecular Pathology, not CAP.

Q. Pardon?

A. I -- I'm not actually sure I answered your question, because you said "had been built," and I said the first time I was there.

Q. I agree.

A. So are you asking me about some critical mass?

Q. Well, you said Illumina was building a presence in the market at that time.

A. Yes.

Q. Okay. So that doesn't give me a date or even a year on which there was awareness in the market. Do you agree with me?

MR. HORNE: Argumentative.

A. Yes.

BY MR. HANKINSON:

Q. And so then my question was when was there an awareness in that market of Illumina-branded products.

MR. HORNE: Vague.

BY MR. HANKINSON:

Q. Is your answer "I don't know," or is it a date?

MR. HORNE: Vague.

A. I don't have a specific date.

BY MR. HANKINSON:

Q. And there is none in your declaration; correct?

A. In my declaration I talk about when we initiated marketing activities.

Q. Which you agree does not give me a date of when an awareness in the market actually existed?

MR. HORNE: Vague, argumentative, mischaracterizes testimony.

Go ahead.

A. I do not -- Yes, I agree.

MR. HANKINSON: You want to take a break?

MR. HORNE: Yep.

(Recess was taken from 9:38 until 9:54 a.m.)

BY MR. HANKINSON:

Q. Welcome back.

A. Thank you.

Q. You understand you're still under oath?

A. Yes.

Q. In any event, you contend that Illumina had started to build brand awareness in the market of

clinical diagnostics as of the year 2007 with the BeadXpress; right?

A. Yes.

Q. And that at least for the last five years Illumina and Meridian have both had FDA cleared IVD products in the clinical diagnostics market?

A. Yes.

Q. And they've both been marketing within that market during that time; right?

A. Yes.

Q. Do you think Illumina has been successful in building an awareness of Illumina and Illumina-branded products in the clinical diagnostics market in that time?

A. Yes.

Q. Do you understand that one of the issues in a case like this one is whether the relevant consumers will be likely to confuse the source of products based on the brand names being too similar?

A. Yes.

Q. And do you understand that where brand names have actually been in the relevant market for a period

of time, one thing that you might look at, being somebody with a science background, is whether the relevant consumers or any of them have actually been measurably confused as to the source of products because of the similarity of the brand names. Does that make sense?

A. Yes.

Q. That that would be one thing that would be relevant, at least?

MR. HORNE: Calls for legal conclusion.

You may answer.

A. Yes, that might be relevant.

BY MR. HANKINSON:

Q. And it would actually be the only type of evidence in a case like this that answers the question "do consumers confuse the source of products based on these two brand names or four brand names being in the same market together for a period of years." Right?

MR. HORNE: Argumentative, calls for a legal conclusion.

A. I don't know whether or not that's the only relevant --

BY MR. HANKINSON:

Q. It would be a measurable piece of evidence, at least, as opposed to predicting like a hypothesis that something is likely to confuse. It would be measuring whether anyone in the market has registered confusion.

MR. HORNE: Argumentative, calls for legal conclusion.

BY MR. HANKINSON:

Q. Right?

MR. HORNE: Sorry.

A. I'm sorry, can you please restate your question.

MR. HANKINSON: Sure. Would you mind repeating. Thank you.

(Question was read)

MR. HORNE: Lacks foundation too.

A. That could be one way of understanding if there is confusion.

BY MR. HANKINSON:

Q. The initial declaration that you submitted in this case and your rebuttal declaration do not identify any actual instances where a relevant consumer reported

being confused between the sources of the products that are branded with the trademarks that are at issue in this case; right?

A. That's true.

MR. HANKINSON: I want to mark this as Exhibit O.

(O'Grady Exhibit O was marked for identification)

BY MR. HANKINSON:

Q. Exhibit O is your company, Illumina's, Supplemental Responses and Objections to Applicant's, Meridian's, First Set of Interrogatories to Illumina, your company; right?

A. Yes.

Q. And if you could turn to page 4. Look at interrogatory number 30. This interrogatory asks "identify and describe each instance of confusion, mistake, or deception of any kind between Opposer's Illumina Marks and Applicant's Illumipro Marks and identify each person with knowledge of each instance."

Do you see that question?

A. Yes.

Q. I'd like you to look at the supplemental response and objections about midway down the page. Are you with me?

A. Right here? Oh, no. Down here.

Q. It says -- this is Illumina's response -- "Subject to and without waiving its objections, Opposer answers that it has not yet documented any instances of confusion between Opposer's Illumina Marks and Applicant's Illumipro Marks by consumers of the parties' goods and services."

Did I read that right?

A. Yes.

Q. So in response to that question, Illumina did not identify any instance of confusion between those marks; correct?

A. Yes. That's correct.

MR. HANKINSON: I'm going to mark this as Exhibit P.

(O'Grady Exhibit P was marked for identification)

BY MR. HANKINSON:

Q. And, first, if you can look at Exhibit O and

flip to where it has a date on it near the back, page 4.

A. Okay.

Q. This response was given as of June 10th, 2013; right?

A. Yes.

Q. So about three years after Illumina actually had FDA-cleared IVD product in the market; right?

A. Yes.

Q. And then if you could look at Exhibit P that I'm handing you now, let's flip and get a date on that one. It would be near the back, page 17. Do you see the date at the bottom?

A. Yes.

Q. So on February 3rd, 2014, Illumina provided these additional supplemental responses and objections to applicant's first set of interrogatories to Opposer that is now Exhibit P; right?

A. Yes.

Q. And in the prior supplemental responses it was interrogatory 30 that we were looking at. If you would please flip through -- the interrogatories go in number along with the responses and supplemental responses --

and get to where it skips from Interrogatory Number 22 to Interrogatory number 32 on pages 12 to 13.

A. On Exhibit P?

Q. On Exhibit P, yeah.

A. I'm sorry, which numbers did you say?

Q. Flip through and just look at the interrogatories being numbered in order. You see how they go through in order?

A. Yeah.

Q. And then when you get to 12 to 13 -- page 12 to 13 --

A. Okay.

Q. -- do you see that it skips from Interrogatory 22 to Interrogatory 32?

A. Yes.

Q. And then as you flip through the rest of it, you'll see they go up in number from there as well.

A. Not every single number but it's increasing.

Q. Right. It skips, right, but they always get bigger?

A. Yeah.

Q. So on February 3rd, 2014, Illumina gave some

supplemental responses and objections, but it didn't give any additional information in response to Interrogatory 30. It skips from 22 to 32; right?

A. Yes.

Q. So there is no additional information about instances of actual confusion in response to Interrogatory 30 in Exhibit P.

MR. HORNE: Lacks foundation, argumentative.

A. I haven't read this document. I don't know if there is something else in here that applies to this. I don't fully understand how they work.

BY MR. HANKINSON:

Q. Sure. But not in response to Interrogatory 30.

A. There is no --

MR. HORNE: Same objections.

BY MR. HANKINSON:

Q. There is no supplemental response to Interrogatory 30?

A. Yes. That does not appear to be in this document.

Q. You understand that if someone in the relevant market had actually been confused about the source of

the products that are branded with the trademarks at issue in this case that that would be good evidence for your company, Illumina, right, because it would show actual confusion?

A. Yes.

Q. So your company would have every interest in the world if they had documents or knowledge of instances of actual confusion to actually identify them in this case so that they could use them before the trademark board; right?

A. I'm sorry, I don't understand the question that you're asking me. What are you asking me?

Q. Illumina would have an interest in identifying instances of actual confusion; right?

A. Yes.

Q. Now, I'm going to talk to Dr. Stephen Young on Friday.

A. Uh-huh.

Q. Are you familiar with who that is?

A. Yes.

Q. And who is he?

A. He is a scientific director at TriCore

Reference Laboratories.

Q. What is TriCore Reference Laboratories?

A. They are a reference laboratory that does diagnostic testing.

Q. Would TriCore Laboratories be a consumer within the relevant market for this case?

MR. HORNE: Lacks foundation, calls for legal conclusion.

A. TriCore is an example of a customer that we attempt to sell products to at Illumina.

BY MR. HANKINSON:

Q. A potential customer?

A. Yes.

Q. And is TriCore also a potential customer of Illumigene and Illumipro-branded products from Meridian?

A. I would assume, yes.

Q. When I ask him on Friday, if I do so, would you expect that Dr. Young will tell me that he thinks the people responsible for purchasing products in his laboratory are likely to be confused as to the source of products, based on products being branded Illumina or IlluminaDX on the one hand, and products being branded

Illumigene and Illumipro, on the other hand?

A. I don't think you asked me a question.

MR. HORNE: Yeah, I was wondering.

MR. HANKINSON: Could you read it back, please.

(Question was read.)

MR. HORNE: Lacks foundation, calls for speculation.

A. I don't know.

BY MR. HANKINSON:

Q. You don't have an expectation one way or the other as to how Dr. Young would answer that question; is that accurate?

A. Yes.

Q. If you could turn to paragraph 31 of your rebuttal declaration, Exhibit M. In addition to Dr. Young you identify --

A. I'm sorry, what did you say? Paragraph 31?

Q. Paragraph 31. In addition to Dr. Young, you identified four other lab directors?

A. Uh-huh, yes.

Q. And do you also not have an expectation one way or the other as to how each of those four lab directors

would answer that question?

MR. HORNE: Lacks foundation, calls for speculation.

A. I don't know what they would say.

BY MR. HANKINSON:

Q. And what about all the other lab directors in the relevant market? Do you have an expectation as to how any of them would answer that question one way or the other?

MR. HORNE: Same objections, compound.

A. I -- yes.

BY MR. HANKINSON:

Q. Would it surprise you if Dr. Young told me that the people responsible for purchasing products at his lab would definitely not be likely to confuse the source of products branded Illumina and IlluminaDX on the one hand, and Illumigene and Illumipro, on the other hand?

A. Yes.

Q. It would surprise you?

A. When you asked me that question, I believe you said would it surprise me if they would definitely not be confused.

Q. Yes.
A. Yes, that would surprise me.
Q. Would it surprise you if he told me that such employees of the lab would not be likely to be confused?
A. Yes, that would surprise me.
Q. Do you know who is responsible for making purchasing decisions for products used to perform clinical diagnostics in Dr. Young's laboratory?
A. Are you asking me --
MR. HORNE: Go ahead. Vague.
A. Are you asking me for a precise name of a person?
BY MR. HANKINSON:
Q. Do you know who it is?
A. No.
Q. Do you know what the person or people's positions are at the lab?
A. I think that -- I don't understand your question.
Q. Do you know the positions of the people or the position of the person who is responsible for making purchasing decisions at Dr. Young's laboratory for

products for use in clinical diagnostics?

A. I know some of the people involved with purchasing decisions, not all of the people involved.

Q. Do you mean personally or their positions?

A. I know of their names and positions.

Q. But there may be other people also sharing responsibility for such purchases that you don't know?

A. Yes.

Q. And you don't know what you don't know? You're not sure how many there are or what their positions would be or even if there are additional people?

A. I know of the people that are the key decision-makers in the purchasing decision. I do not know of lower level people that may be involved.

Q. And what are the positions of the people that you are saying are the key decision-makers?

A. Steve Young is an example of a key decision-maker.

Q. He's the lab director?

A. Laboratory director. There is another individual that we've been in contact with that is a cytogenetics lead. His name is Dr. Hozier.

Q. Is your answer complete?

A. Yes.

Q. So those are the people, Dr. Young, himself, and Dr. Hozier, cytogenetics lead, who you are thinking about when you say you would be surprised if Dr. Young told me that he and Dr. Hozier were not likely to be confused between the sources of the products branded that are at issue in this case?

MR. HORNE: Mischaracterizes testimony.

A. No.

BY MR. HANKINSON:

Q. So who are the people you were talking about?

A. Individuals placing orders for products.

Q. What are those individuals' positions?

A. I don't know.

Q. Do you know if those people are medical or research personnel, as opposed to people who are in a purchasing function at the lab or an administrative function?

A. I do not know.

Q. It could be either?

A. Could be either.

Q. So you don't know who the people that are making the purchasing decisions that you think are likely to be confused, and yet you do think that they are likely to be confused?

MR. HORNE: Vague, mischaracterizes testimony.

A. Can you restate the question?

MR. HANKINSON: Uh-huh. Would you mind? Thank you.

(Question was read)

A. The -- the part of that that is causing me pause is the purchasing decision. Individuals that are placing the order may or may not be involved with the decision itself. They may be following directions and placing an order.

BY MR. HANKINSON:

Q. I'm having trouble following your line of logic.

MR. HORNE: Argumentative.

BY MR. HANKINSON:

Q. I asked you if you would be surprised that Dr. Young -- I asked you if you would be surprised if Dr. Young told me that the people at his lab responsible

for purchasing decisions were not likely to be confused, and you said that would surprise you.

A. Uh-huh.

Q. And then I asked you who the people responsible for purchasing decisions were, if you knew who they were.

A. Uh-huh.

Q. And you said you knew two key decision-makers, Dr. Young, himself, and Dr. Hozier; right?

A. Uh-huh.

Q. And then you said -- and then I asked you if those were the people you were talking about that you thought Dr. Young would say were likely to be confused, and you said no. And then you said that there are other individuals placing orders for products; and then you said that you don't know what positions they are, whether they are administrative or medical or research, even.

And then I said is that who you were talking about, and you said no.

MR. HORNE: Argumentative, object to the extent it mischaracterizes testimony.

A. I'm sorry, I didn't understand the last part of what you said.

BY MR. HANKINSON:

Q. You said there were people placing orders for products.

A. Yeah.

Q. Is that who you were saying you thought Dr. Young would find to be likely to be confused?

A. I -- when I answered your question about would I be surprised if someone would -- if there was no opportunity for confusion, would I be surprised by that. Yes, I would be surprised by that.

Q. Then I followed up and asked about likelihood of confusion.

A. Yeah.

Q. And you still said you'd be surprised?

A. Yes. I do think there is opportunity for confusion.

Q. That doesn't answer the question.

MR. HORNE: Argumentative.

A. I'm sorry, what is the question?

////////

BY MR. HANKINSON:

Q. So I asked you if it would surprise you if Dr. Young told me that the people at his lab --

A. Uh-huh.

Q. -- responsible for making purchasing decisions would not be likely to be confused with the source of the products whose brands are at issue in this case; and you said yeah, that would surprise you.

And I said, well, do you know who the people responsible in his lab are. Are you with me so far?

A. Yes.

Q. And then you identified the two key decision-makers, Dr. Young, himself, and Dr. Hozier.

A. Uh-huh.

Q. I asked are those the people you're talking about, but you think -- and you said no.

A. Uh-huh.

Q. So the key decision-makers at Dr. Young's lab, it would not surprise you to find that they don't think they are likely to be confused between the sources of the products at issue?

MR. HORNE: Argumentative, mischaracterizes the

testimony.

BY MR. HANKINSON:

Q. It was somebody else?

A. I'm having a hard time following the double negatives. Can you please restate it.

Q. You've been answering my questions.

A. The last question that you just asked me there were a few double negatives. I'm having a hard time following.

Q. So just the last question?

A. Just the last question.

Q. So we were on the same page up until the last question?

A. Yes.

Q. So as to the key decision-makers, Dr. Young and Dr. Hozier --

A. Yes.

Q. -- you don't think that Dr. Young will tell me that he and Dr. Hozier are likely to be confused as to the sources of the products whose brands are at issue in this case?

MR. HORNE: Mischaracterizes testimony.

A. I don't know whether or not they are -- those individuals are likely to be confused.

BY MR. HANKINSON:

Q. They might be?

A. They might be.

Q. Or they might not be?

A. They might not be.

Q. So neither answer would surprise you as to them?

A. No.

Q. And then you said it would surprise you as to people responsible for purchasing decisions at his lab.

Do you want to retract that answer, or is there somebody you have in mind?

A. Dr. Young, to my knowledge, is heavily involved with decision-making in executing the laboratory, and I presume he is not placing orders himself. I would be surprised if other individuals involved supporting him would have no opportunity for confusion.

Q. And that's all you're saying?

A. That's all I'm saying.

Q. Would you say the same for the other four labs

and lab directors in paragraph 31 of your declaration?

A. I wouldn't generalize for every laboratory.

Q. So if someone was going to prove that the brands at issue in this case were likely to cause confusion between the sources of the products, you don't think that the person trying to prove that could generalize between the various labs in the market?

MR. HORNE: Vague, compound, argumentative, mischaracterizes testimony.

BY MR. HANKINSON:

Q. Would it be different in each lab?

MR. HORNE: Calls for legal conclusion.

BY MR. HANKINSON:

Q. Call for different facts?

A. I believe the level or relative exposure to these products plays a role in opportunity for confusion, how long they've been involved with the product.

Q. You think that confusion would be more likely to arise early in someone's exposure to the brands at issue and less likely to arise once they've had more exposure to the brands at issue?

A. In general, confusion is something I think people seek to resolve.

Q. So that later in time as more exposure to the brands at issue has been experienced by the relevant decision-makers, you think it's less and less likely that there would be confusion in the marketplace because people tend to resolve that confusion if there is some over time?

MR. HORNE: Vague, incomplete hypothetical.

A. No. I don't agree with what you said.

BY MR. HANKINSON:

Q. So your answer, the pithy one about you think people tend to resolve confusion over time, didn't answer my question, because I was asking about specific consumers in a specific market.

A. Okay.

MR. HORNE: Argumentative.

BY MR. HANKINSON:

Q. So do you think that there would be -- it would become less and less likely over time as the consumers in the relevant market are more and more exposed to the brands at issue that they would be confused?

MR. HORNE: Vague, incomplete hypothetical.

A. I don't know.

BY MR. HANKINSON:

Q. And anything in your rebuttal declaration or initial declaration that someone might interpret to be giving an opinion on whether consumers in the relevant market would be likely to be confused or not likely to be confused should not be interpreted in that way because you do not have such an opinion; right?

MR. HORNE: Vague, compound, mischaracterizes testimony.

A. I don't understand what you're saying to generalize it to everything I've ever said before.

BY MR. HANKINSON:

Q. You are telling me that you cannot generalize the answers of whether you think that the decision-makers at laboratories would be confused, even across five laboratories that you specifically listed in paragraph 31?

A. Uh-huh.

Q. They each have to be taken individually; right?

MR. HORNE: Mischaracterizes testimony.

A. I do not think the amount of confusion that may be experienced by the five labs listed here could be generalized to the entire market.

BY MR. HANKINSON:

Q. Why?

A. Because these individuals represent people that we have -- actually I don't want to generalize all of them, because the place where they are in their buyer's journey is relevant to the level of confusion.

Q. What's the end of their buyer's journey?

A. Ideally there should be no end. We continue to sell products and build upon it.

Q. So the end, if there is one, ideally would be a continuing relationship where additional purchases are made over time?

A. No.

Q. And prior to that there -- on any buyer's journey would be the first time that that buyer purchases a product from Illumina?

A. I'm sorry, could you restate that?

Q. Prior to that ideal relationship, there would have to be in each buyer's journey a time when that

buyer purchases their first Illumina product.

A. Yes.

Q. What's the stage on the buyer's journey that immediately precedes that first sale?

A. Negotiation.

Q. Is there a typical amount of time that a buyer takes in the negotiation stage of the buyer's journey, or does it vary across the board?

A. It varies.

Q. What's the stage in the buyer's journey that immediately precedes negotiation?

A. Decision-making or choosing a solution.

Q. And is there a set amount of time that that typically takes in clinical diagnostics, or does it vary across the board?

A. It's variable.

Q. What stage in the buyer's journey in the field of clinical diagnostics immediately precedes decision-making or choosing a solution?

A. I wouldn't necessarily generalize the term "buyer's journey" to the field of diagnostics.

Q. It encompasses both the field of diagnostics

and other fields?

A. The term "buyer's journey" is a marketing strategy that we use at Illumina.

Q. And you believe that in the field of clinical diagnostics the place where the consumer is on the buyer's journey is relevant to the level of confusion, in your opinion?

A. Yes.

Q. And so what immediately precedes the phase of the buyer's journey that you call decision-making or choosing a solution?

A. Considering alternatives.

Q. Does that have a typical amount of time that it takes, or does it vary across the board?

A. It's variable.

Q. What's the phase that immediately precedes considering alternatives on the buyer's journey?

A. A proposed solution.

Q. Does that have a typical amount of time that it takes, or does it vary?

A. Variable.

Q. What phase of the buyer's journey immediately

precedes a proposed solution?

A. Understanding a problem.

Q. Does that have a typical amount of time that it takes, or does it vary?

A. It's variable.

Q. Is there a phase preceding understanding a problem?

A. Awareness of a need.

Q. Is there a phase before that?

A. I don't think so.

Q. And in saying -- you said that the place where a customer is on their buyer's journey is relevant to the level of confusion. I got that right; right?

A. Yes.

Q. And you said that people tend to resolve confusion over time?

A. Yes.

Q. And so I'm assuming that when you say that the place where they are in their buyer's journey is relevant as they go through the course of their buyer's journey they become less likely to be confused. Do I have that right?

A. Yes.

Q. So if I were to draw a graph of it where the Y axis is the likelihood of the customer being confused and the X axis is stages of the buyer's journey, the likelihood of confusion, in your opinion, would start somewhere up on the Y axis and then it would be a diagonal line going down toward the X axis along the way?

MR. HORNE: Vague, incomplete hypothetical.

A. I'm having a hard time following you. I'm having a hard time following what you said.

BY MR. HANKINSON:

Q. What's the shortest amount of time in your opinion that a customer in the clinical diagnostics field has gone through the buyer's journey?

A. I don't know.

Q. What's the longest amount of time in your experience?

A. I don't know.

Q. Are there different personnel at a customer in the field of molecular diagnostics who would be involved in different stages of the buyer's journey?

A. It's possible, yes.

Q. When is someone from Illumina first involved in the customer's buyer journey? At what phase?

A. The -- all of them.

Q. So what type of position of personnel from Illumina is involved in the buyer's journey phase awareness of a need?

A. It could be -- it could be anyone.

Q. Is your answer going to be the same for who from Illumina is involved in the buyer's journey as to all the different phases, or does it get more specific?

A. A customer could enter any stage of the buyer's journey through an interaction with a new sort of person at Illumina.

Q. Not the janitor, I assume?

A. No. I would assume not the janitor.

Q. Typically someone who is in marketing or research and development or comes into contact with them through a trade show or some sort of marketing piece; right?

A. Or sales or field support.

Q. And from the point that an Illumina person in

marketing, sales field support or somebody who comes in contact with the customer through a trade show or some sort of marketing activity becomes involved, the Illumina personnel will help the buyer through their buyer's journey; right?

A. Yes.

Q. And if the customer is confused as to the source of a branded product, the Illumina people involved in helping them through the buyer's journey would explain to them the source of that product; right?

A. If a customer expressed confusion, you would seek to correct it.

Q. And if a customer asked the Illumina personnel that are helping them through their buyer's journey to provide a product that Illumina doesn't make, that some other company made, then the Illumina personnel would explain that to them and clear up that confusion; correct?

A. I would assume that to be true.

Q. At some point before the actual sale; right?

A. If the individuals involved with placing the order have communicated with an Illumina person,

then -- and shared confusion, I would expect them to clear it up.

Q. And if the personnel involved in helping consumers in the field of molecular diagnostics through their buyer's journey were aware of the consumer mistakenly believing that the Illumigene product or the Illumipro product came from Illumina, would you expect those Illumina personnel to tell their supervisors that that had happened?

A. I don't know.

Q. Are there products that Illumina offers for sale that don't involve the negotiation stage?

A. Yes.

Q. What products?

A. Some of our products are orderable online and don't require negotiation, mainly consumables.

Q. When a consumer makes an online purchase of consumables, does Illumina attempt to form a relationship between Illumina personnel and the consumer?

A. I don't know.

Q. Consumers are assigned an account manager;

right?

A. Yes.

Q. And that account manager's job includes forming a relationship and familiarity with the consumers that they are assigned to; is that right?

A. Yes.

Q. So you do know. I mean that is something Illumina attempts.

A. I assumed you meant every time. I don't know every time if that happens.

Q. So --

A. Sometimes it happens.

Q. -- some account managers might not be doing their jobs?

A. No. That's not what I said.

Q. Sometimes an account manager is not assigned?

A. There may be an example of a lab tech placing an order that is not directly communicating with the sales rep. The sales rep may be speaking to someone higher level than that. I don't know if every person that places an order talks to a sales rep.

Q. Oh. So in the exceptions to what we're talking

about, account managers are actually speaking to someone at that organization that's purchasing the product but it might not be the person who placed the online order?

A. Illumina sells products of -- I don't -- I don't know if every circumstance a sales rep is communicating with a customer directly when they place an order. They may or may not be.

Q. Does Illumina prefer that an account manager have a relationship with the consumer?

A. For high value accounts, yes.

Q. Do you know what percentage of Illumina's accounts are considered high value versus other?

A. No.

Q. Do you know if it's more than half?

A. No.

Q. Do you know if it's -- so you just have no idea?

A. I don't know.

Q. So the amount of interaction between Illumina personnel and the customer just cannot be generalized across different consumers in the clinical diagnostics field?

MR. HORNE: Argumentative.

A. I don't know. I don't know.

BY MR. HANKINSON:

Q. Every customer will come in contact with Illumina at a different place along the buyer's journey; right?

A. Yes.

Q. And Illumina will have a different reaction to that based upon if they are a high value account or not? Yes?

A. What I'm trying to say is --

Q. Could you first answer my question. Illumina will have a different level of reaction to that, depending on whether they are a high value account or not?

A. No.

Q. The reaction from Illumina will be the same, no matter whether they are high value or not? Because you just told me that some get account managers based if they are high value and some don't.

A. I said that the level of interaction from an account manager would be relative to the value of the

account.

Q. And if your prior answer was not that but in fact something different, then your prior answer was inaccurate?

MR. HORNE: Vague, argumentative.

A. I believe I said the same thing before.

BY MR. HANKINSON:

Q. And if that's not true, then before you misstated it? That's what you intended to say before?

MR. HORNE: Vague.

A. I'm --

BY MR. HORNE:

Q. Why is that hard?

A. Because I'm trying to answer your question, and I feel like we're nit-picking on words.

Q. I feel like you're nit-picking on words and I'm just trying to get you to give me an answer.

MR. HORNE: Argumentative.

A. The -- Illumina sells some products online that are low cost; and if a customer orders something that's low cost, we're not going to send a sales rep there. They may or may not have an account manager. I would

assume they do have an account manager, but whether they are going to call that person because of an enzyme order, I don't assume that's how the sales rep is spending their time.

BY MR. HANKINSON:

Q. But they do have an account manager?

A. Yeah.

Q. And that account manager is the person responsible from Illumina's side for the relationship with that consumer; right?

A. Yes.

MR. HORNE: Let me know when you're ready for a break, Tom.

BY MR. HANKINSON:

Q. Is the account manager from Illumina involved in the negotiation stage of the buyer's journey?

A. Yes.

Q. And the account manager is knowledgeable about the products that Illumina offers?

A. Yes.

Q. Is the account manager knowledgeable about competitive products?

A. Yes.

Q. Does the account manager take responsibility for answering the questions of the customer during the various stages of the buyer's journey with respect to the solutions that Illumina offers and the solutions that a competing company offers?

A. Yes.

Q. By the time the negotiation stage of the buyer's journey happens, the customer knows the competing solutions and which come from Illumina; right?

A. Yes.

Q. And after the negotiation the customer makes a purchase?

A. Yes.

Q. Do you think that this level of contact and explanation between the marketers of medical and research products and devices and the customers in the clinical diagnostics field explains why there have been no reported instances of actual confusion between the brands at issue in this case?

MR. HORNE: Lacks foundation.

A. I don't know.

BY MR. HANKINSON:

Q. It's certainly a contributing factor; right?

MR. HORNE: Argumentative.

A. I don't know how those things are related.

BY MR. HANKINSON:

Q. In paragraphs 33 and 34 of your declaration you talk about pricing of Illumina products; right?

A. Yes.

Q. When you attended a deposition in December, do you remember me asking you what the cheapest instrument that Illumina offers is?

A. I don't remember you asking me that.

Q. Do you remember telling me that the cheapest instrument Illumina offers costs $35,000, roughly?

A. I don't recall that conversation.

MR. HORNE: Another request for a break when you've got a minute, Tom.

MR. HANKINSON: Okay. Five minutes. Does that work?

Will you mark this as Exhibit Q, please.

(O'Grady Exhibit Q was marked for identification)

BY MR. HANKINSON:

Q. Exhibit Q is a transcript of your deposition from December 4th, 2014. Do you see that?

A. Yes.

Q. Do you remember sitting I believe in this very same room answering questions that I was asking on that day?

A. Yes.

Q. And you were under oath that day, as you are today; right --

A. Yes.

Q. -- to tell truth?

A. Yes.

Q. Did you intend to give me your full knowledge responsive to my questions at that time?

A. Yes.

Q. Could you turn to page 23. There's four page numbers on each page of this Exhibit Q. Page 23 of your deposition.

A. Yes.

Q. Actually on page 22 we talk about array and sequencing platforms around line 14. Do you see that?

A. Yes.

Q. And I asked if those are machines that are sold to laboratories, and you said yes; right?

A. We're on page 23, number --

Q. 22. We're on line 14 to 17.

A. Yes.

Q. And then on page 23 at the top I asked you what the other machines are, and you named some; right?

A. Yes.

Q. And then I asked you what the cheapest one was. Do you see that?

A. Yes.

Q. You said you didn't remember the exact price; right?

A. Yes.

Q. And you said it was more than $10,000; right?

A. Yes.

Q. And you said it's in the realm of $30- to $50,000; right?

A. Yes.

Q. And during that deposition you did not say anything about machines being available at no cost to

customers; correct?

A. I don't think so.

MR. HANKINSON: Okay. We can take a break.

(Recess was taken from 11:01 until 11:13 a.m.)

BY MR. HANKINSON:

Q. Could you look at Exhibit M, your rebuttal declaration again, please, and specifically paragraph 4.

A. Uh-huh.

Q. Second, as also explained elsewhere in this declaration, clinical diagnostics labs are not always separated by application segment as Mr. Kozak states in paragraphs 30 and 31 of his declaration?

A. Yes.

Q. By application segment, what do you mean?

A. The testing segment where the technology is applied.

Q. What's an example of one segment?

A. Genetic testing.

Q. What's an example of another segment?

A. Cancer.

Q. And another?

A. Infectious disease.

Q. When you say they are not always separated by application segment, you do not provide a percentage of how often they are separated by application segment in your declaration; correct?

A. Yes, that's correct.

Q. In paragraph 7 you have a paragraph-long definition of molecular pathology; correct?

A. Yes.

Q. In your rebuttal declaration you do not provide a citation for this definition; correct?

A. That's correct.

Q. And in your rebuttal declaration you do not provide an explanation of your source for this definition; correct?

A. That's correct.

Q. In your rebuttal declaration you do not express what education or experience you have that permits you you to opine on what the definition of molecular pathology is; correct?

A. That is correct.

Q. In the last sentence of paragraph 7 you state, "thus when the products are used for the purpose of

diagnosing patients, they both also fall within the subcategory of molecular diagnostics."

Do you see that sentence?

A. Yes.

Q. And then the corollary of that is when the products are not used for the purpose of diagnosing patients, then they would not both fall within the subcategory of molecular diagnostics; correct?

A. When products are not used for diagnosing patients, they are not -- are you asking me when products are not used for diagnosing patients does that classify as molecular diagnostics? Is that what you're asking me?

Q. Correct. I think it's just the logical conclusion that's implicit in what you've said in the last sentence of paragraph 7.

A. I don't mean to be difficult, but diagnosis is an action. You can diagnose a disease. You can also look at prognosis or therapeutic response, but I think for what you're trying to say that research and -- I'll just stop there.

Q. So in your declaration when you talk about

diagnostics, it is -- it cannot be assumed whether you're talking about treating patients or using -- or the prognosis of patients or the therapeutic response of patients. It could encompass any or all of those terms?

A. It's intended to encompass them all.

Q. But treating patients is a particular type of diagnostics; correct?

A. Not necessarily.

Q. Well, it's the one that the FDA regulates with cleared products; right?

A. Not necessarily.

Q. Does the FDA require IVD products to be cleared if they are only going to be used in therapeutic response aspects of molecular diagnostics?

A. Not -- I don't want to speculate. I can imagine examples that that's not the case.

Q. But they would be speculation?

A. I know of examples where that's not the case.

Q. So it wouldn't be speculating?

A. I don't want to speculate that all examples of molecular testing where someone is trying to look for therapeutic response requires an IVD. That's what I'm

not comfortable speculating on.

Q. Right. It may or may not.

A. It may or may not.

Q. Whereas all diagnostics tools used for treating patients would be required to have FDA clearance as IVD products?

MR. HORNE: Lacks foundation, argumentative, vague.

A. I don't know.

BY MR. HANKINSON:

Q. And some labs -- it doesn't matter. It's a flexible concept that encompasses various aspects of disease identification, treatment, prognosis, therapeutic response; and any given lab or physician could be doing one or more of those. Is that fair to say?

A. What's the subject of "it"?

Q. Molecular diagnostics, in your opinion.

A. Yes. That's a fair statement.

Q. In paragraph 9 you state that "Illumina rents customer lists from one or more of the aforementioned associations, and it sends marketing materials covering

the whole range of its products to the potential customers indicated on the list. Under this umbrella approach to marketing there is no consideration given to any particular customer's specialty (assuming a customer even has a specialty)."

Do you see that?

A. Uh-huh, yes.

Q. So in this paragraph you're saying that Illumina was taking an umbrella approach to marketing that gave no consideration to the particular customer's specialty, right, with respect to these email lists?

MR. HORNE: Lacks foundation, mischaracterizes the document.

A. This paragraph describes lists. It doesn't specify if the communication is by email or direct mail or what have you.

BY MR. HANKINSON:

Q. So it's more general than what I said? This applies to all of those things?

A. Yes.

MR. HORNE: Vague.

MR. HANKINSON: Sorry about that.

Q. So as to all of those things under this umbrella approach to marketing, there is no consideration given to any particular customer's specialty. That's what this approach means; right?

A. Yes.

Q. So to the extent that earlier today you told me that there were particular targets of -- that were meant to be reached with Illumina's branding through these customer lists divided up by specialty, that's not what you intended to say?

A. I don't -- I don't remember saying that.

Q. Well, you told me that these rented customer lists were used to target clinical diagnostics with marketing intentionally?

A. Yes.

Q. Okay. This says "there is no consideration given to any particular customer specialty," in paragraph 9; right?

A. By "specialty," I am not implying diagnostics or otherwise but a subspecialty of that field.

Q. Do you think that's a little misleading, given that the paragraphs leading up to it all talk about

molecular pathologists as a whole, as opposed to dividing it up between clinical diagnostics and other molecular pathology and has no reference to any particular subcategory, subspecialty other than that?

MR. HORNE: Argumentative.

A. I don't know.

BY MR. HANKINSON:

Q. In any event, now you're saying that paragraph 9 refers to no consideration being given to whether a particular customer is in infectious disease, as opposed to genetics, as opposed to cancer and the other of what you called application segments?

A. Yes, that's correct.

Q. So none of those particular application segments were being targeted. They just happened to be within the list?

MR. HORNE: Vague.

A. They were not excluded.

BY MR. HANKINSON:

Q. Could you answer my question, though?

A. We did not take the option to exclude them. They are included.

I'm sorry, what is the question?

Q. So there is an option to exclude infectious disease?

A. Yes.

Q. And you chose not to take that option?

A. That's right.

Q. And that's the status of this umbrella approach?

A. Yes.

Q. Thank you. Would you look at paragraph 10. "Throughout" -- you state, "Throughout his declaration Mr. Kozak suggests that Illumina's products have only been used in research labs and not in clinical diagnostics labs."

Do you see that?

A. Yes.

Q. Do you understand that whether or not something is used in a lab is a different concept from whether or not that lab is a relevant consumer for purposes of deciding whether brands are likely to be confused with each other?

MR. HORNE: Lacks foundation, argumentative,

calls for legal conclusion.

A. I don't have an opinion about that.

BY MR. HANKINSON:

Q. And so when your declaration is talking about whether a product is used in a lab, you're not making an assertion about whether that makes that lab a relevant consumer or someone who is aware of the branding in a particular field of product. You're just saying it happened to be used in a lab?

MR. HORNE: Vague.

A. I don't know.

BY MR. HANKINSON:

Q. Do you understand that Mr. Kozak is talking about in his declaration a market for products, as opposed to entities who just happen to have products in the room?

MR. HORNE: Vague, lacks foundation.

A. I understand what you just said.

BY MR. HANKINSON:

Q. "I do" or "I don't"?

A. I understand what you just said.

Q. But you don't understand that one way or the

other, in your own opinion, as to Mr. Kozak's statement?

A. I'm sorry, I don't understand the question that you're asking me. What are you asking me?

Q. When I asked you if you understand something, a couple times you said "I understand what you just said," like the words that came out of my mouth, which isn't really answering the question of whether you understand it to be true.

I'd like you to tell me whether you understand it to be true that Mr. Kozak in his declaration was talking about a market.

A. Uh-huh.

Q. "Yes"?

A. Yes.

Q. And what the relevant market for the products at issue is or is not; right?

A. Yes.

MR. HORNE: Lacks foundation, vague.

BY MR. HANKINSON:

Q. What you're talking about in this paragraph is whether or not a RUO-labeled product could be used in theory in a particular kind of lab; right?

MR. HORNE: Mischaracterizes the document.

A. No. That's not right.

BY MR. HANKINSON:

Q. So what are you saying that I'm not understanding?

A. The products listed here, MiSeq, HiSeq, NextSeq -- including MiSeq, HiSeq, NextSeq, BeadArray Reader, iScan, and BeadXpress have been used in clinical diagnostic labs and they represent a market for our products.

Q. That's what you're asserting in paragraph 10?

A. Yes.

Q. That these RUO-labeled products, having been used by labs in laboratory-developed tests, were, therefore, part of the clinical diagnostics market? That's what you're saying?

A. Yes. They were consumed by consumers in the clinical diagnostic market.

Q. And that, therefore, you're saying that Illumina had already had a presence in the clinical diagnostics market, even though it was only marketing RUO-labeled products; right?

A. Yes.

Q. And you're saying, therefore, that it was not a big transition when Illumina actually had IVD devices cleared by the FDA, because they were already a participant in that clinical diagnostics market?

A. Yes.

Q. You wouldn't have considered it a transitional step from RUO research market to the clinical diagnostics market? That's what you're saying here?

A. I don't know what you mean by "transitional step," in what way you mean that.

Q. Well, a transition is a change from one thing to the other.

A. Yes.

Q. So transitional is an adjective that describes changing one thing into the other?

A. Yes.

Q. I'm not -- I'm just working my way through. I'm not trying to be pedantic. Although I am naturally, I'm not trying to be.

And so the -- I'm asking you is it your contention that the step of Illumina having only

RUO-labeled products in clinical diagnostics laboratories and other laboratories to the clinical diagnostics field was not a transitional step but just more of the same presence in the market.

MR. HORNE: Vague.

A. I would consider actually approval building on our presence in the market.

BY MR. HANKINSON:

Q. As opposed to how I just described it as a transitional step?

A. I am --

MR. HORNE: Same objection.

A. I'm having a hard time distinguishing between the two.

BY MR. HANKINSON:

Q. When you stay at one company you build upon your experience with that company and you're there, right, in a career?

A. Uh-huh, yes.

Q. And when you transition to another company, you're changing to somewhere else?

A. Yes.

Q. So that's a transitional step, as opposed to building within the same category of where you were. You're transitioning to something different; right?

A. Yes.

Q. You understand that to be the meaning of "transitional"?

A. Yes.

Q. And so I'm asking in this paragraph 10 --

A. Uh-huh.

Q. -- you are asserting that because Illumina already had RUO-labeled products being used by labs and laboratory-developed tests for clinical diagnostics, it was not a transitional step to enter the field of clinical diagnostics?

MR. HORNE: Calls for legal conclusion.

BY MR. HANKINSON:

Q. It was more of being in that market already. That's what you're saying; right?

MR. HORNE: Same objection.

BY MR. HANKINSON:

Q. We don't have to belabor it.

A. I don't understand the distinction.

Q. You're saying it was a transitional step?

A. Some things change and some things were built upon. I don't -- I'm having a hard time understanding what you're asking me, to answer your question; and I guess if I don't see a big transformation then the answer is no.

Q. So if I said is it a big transformation from RUO-labeled products being present in clinical diagnostics laboratories through laboratory-developed tests to FDA-cleared IVD products, you'd say no, that's not a big transformation?

MR. HORNE: Vague.

A. From whose perspective?

BY MR. HANKINSON:

Q. The market's perspective.

A. No. I don't think that's a big transition.

Q. And it's not entering into a field, is what you're saying. It's continuing to be in the field of clinical diagnostics. That's what you're saying in paragraph 10; right?

A. Yes, continuing and building upon.

MR. HANKINSON: I want to mark as an

exhibit -- actually we don't need to mark it. It's been identified as -- I don't know. Didn't both sides number their exhibits?

MR. HORNE: Yeah.

MR. HANKINSON: All right. So maybe we should mark it. I want to mark this.

MR. HORNE: If you're going to use it -- if it was already marked as an exhibit number, it may be easiest to keep the same exhibit numbers.

MR. HANKINSON: Yeah, I remember talking about that last time, but then it struck me that didn't Meridian and Illumina both sequentially number starting at 1?

MR. HORNE: That I don't know about. You may have started -- you guys did yours after we did her deposition; so I can't remember.

MR. HANKINSON: Let's mark this as R.

(O'Grady Exhibit R was marked for identification)

BY MR. HANKINSON:

Q. So Exhibit R is a press release that Illumina provided in this matter to Meridian entitled, "Illumina

Receives FDA 510(k) clearance for its BeadXpress Multiplex Analysis System." Correct?

A. Yes.

Q. This is authored by Illumina; right?

A. Yes.

Q. And it's meant to be provided to publications for them to use and then spreading word about what is in the press release; right?

A. Yes.

Q. And when Illumina's CEO makes statements in a press release that are intended to go out to the public, do you think it's important that he try to be accurate and clear in that communication?

A. Yes.

Q. And do you think that Illumina's CEO, Jay Flatley, always does try to be accurate and clear when providing information to the public?

A. Yes.

Q. And could you look at the second paragraph. The first sentence says, "This approval," meaning the FDA 510(k) clearance of BeadXpress, "represents a significant and exciting transitional step for Illumina

into the diagnostics field."

Do you see that?

A. Yes.

Q. And that's a quote from Jay Flatley, the president and CEO of Illumina; right?

MR. HORNE: I object, it's a partial quote.

BY MR. HANKINSON:

Q. It's the first part of the quote.

A. Yes.

Q. The second part of the quote is "where the potential is great for molecular medicine to make a real difference in the way disease is detected and ultimately prevent it and treat it, said Jay Flatley, president and CEO."

That's the rest of it; right?

A. Yes.

MR. HORNE: Objection. I believe the quote continues in the paragraph.

MR. HANKINSON: All right.

Q. Miss O'Grady, would you please read paragraph 2 and indicate what's being quoted by quote and unquote.

A. From the beginning?

Q. Yes, please.

A. Quote, "This approval represents a significant and exciting transitional step for Illumina and to the diagnostics field. Our potential is great for molecular medicine to make a real difference in the way disease is detected and ultimately prevent it and treat it," quote, "said Jay Flatley, president and CEO," period.

Quotation, "It demonstrates Illumina's ability to meet stringent regulatory requirements in designing and manufacturing an FDA-cleared in vitro diagnostic device."

"This will serve as an important foundation for our future plans in the diagnostic area. Ultimately, our goal is to become a leader in the translational medicine focusing on complex diseases that benefit from high performance analysis, including genotyping, copy number, gene expression, methylation and protein analysis."

Q. Your opinion expressed in paragraph 10 of Exhibit M, your rebuttal declaration, was that a move from simply having RUO-labeled products that were in clinical diagnostics laboratories, who used them in

laboratory-developed tests, to having FDA-cleared IVD devices was not a big transformation and was not entering into a new field but rather was not a big transformation and was simply continuing in a field where there is already a presence.

Do I have that right?

A. Yes, that's correct.

Q. In Exhibit R, Jay Flatley is quoted as saying that the FDA clearance for BeadXpress, which was in 2010, was a significant and exciting transitional step for Illumina into the diagnostics field; right?

A. Yes. He states that.

Q. And are you still of the opinion that you express in paragraph 10?

A. Yes.

Q. You do believe that Mr. Flatley was trying to be clear and correct when he made that statement; right?

A. Yes.

MR. HANKINSON: I'm going to mark this as Exhibit S.

(O'Grady Exhibit S was marked for identification)

BY MR. HANKINSON:

Q. Exhibit S is an article from GenomeWeb; right?

A. Yes.

Q. As produced by your company in this matter with the ILLUM bates numbers at the bottom.

A. I'm sorry, what did you ask?

Q. Was this produced by your company in this litigation?

A. Yes.

Q. And I believe it was Karen Possemato who refers to GenomeWeb as a relevant publication that goes to consumers that are within the market of clinical diagnostics.

A. Among others, yes.

Q. In January of 2009 GenomeWeb published the article "Illumina Unveils Strategy to Enter Molecular Diagnostics Market"; right?

A. Yes. That's the title of this publication.

Q. So a consumer in the clinical diagnostics market who saw this at the time would understand that Illumina was unveiling a strategy to enter the molecular diagnostics market, as opposed to continue to be in it;

right?

MR. HORNE: Argumentative, lacks foundation.

A. No. I disagree.

BY MR. HANKINSON:

Q. The first sentence is "Illumina plans to enter the molecular diagnostics space"; right?

A. Yes. That's the first part of that sentence.

Q. It says in full, "Illumina plans to enter the molecular diagnostics space by forging partnerships with customers, opening a new CLIA lab, and launching a research project to study cancer genomes, CEO Jay Flatley said during a recent presentation to investors."

Do you see that?

A. Yes.

Q. When a CEO speaks to investors, is he under a duty to be truthful and forthright?

A. Yes, I assume.

Q. Are you aware of any time when Illumina or its CEO Jay Flatley has retracted statements that were made by Mr. Flatley to investors or to journalists?

A. I'm not aware of any statements.

Q. Do you think that the statement from

Mr. Flatley was misleading to the consumers who read GenomeWeb?

A. No.

Q. In paragraph 13 of your rebuttal declaration, Exhibit M, you state "Illumina's instruments, for example" --

A. I'm sorry, where again?

Q. Paragraph 13. "Illumina's instruments, for example, MiSeq, HiSeq, NextSeq, BeadArray Reader, iScan, BeadXpress may be used by LDT developers to detect DNA."

A. Yes.

Q. When you say "may be used," do you supply in your rebuttal declaration any statement of how often as a percentage those are used by LDT developers out of the entire market of clinical diagnostics?

A. No.

Q. The last sentence on paragraph 3 going to -- excuse me -- on page 3, going to page 4, you state, "In addition the LDT developers that use Illumina's instruments also often use Illumina's reagents. In sample preparation assays which are read by the Illumina instrument, similarly Meridian provides

Illumigene assays that prepare a sample to be read by its Illumipro instruments."

Right?

A. Yes.

Q. And when a reagent in sample preparation assays are read by an Illumina instrument, what kinds of data are reported?

A. It depends on the question being asked, what the purpose of it is.

Q. It's open to the user to seek different sorts of data; correct? That's what you mean when you say it depends on the question being asked?

A. No. That's not what I mean.

Q. You can ask an Illumina reader different kinds of questions and you get different types of data out of it; right?

A. The types of data that Illumina's systems that are referred to in this paragraph provide are variant calls or copy number variation calls, measures of variation in DNA and RNA.

Q. You said it depends on the question being asked.

A. Yes.

Q. Okay. So it's different depending on the question being asked?

A. It's different based on the sample preparation assay that the customer chose to use.

Q. So the customer prepares the sample preparation assay?

A. They choose a sample preparation assay and execute it in their lab.

Q. You're saying Illumina provides the reagents, but that's not everything that's in the sample preparation assay; right?

A. We provide complete sample preparation kits.

Q. The customer chooses what sample preparation assay to use?

A. Yes.

Q. Is that the only variation that you meant when you said it depends on the question being asked?

A. No.

Q. So what other variations are there?

A. The software analysis selected.

Q. So there is software in the Illumina reader

that allows you to look at different types of data?

A. There is software available that allows a user to look at different types of data.

Q. Available from Illumina?

A. Available from Illumina.

Q. And is that -- Are those the only two variations that you meant when you said that it depends on the question being asked?

A. The other potential variation would be the instrument selected. There is six listed here.

Q. They each do something a little different?

A. They can all be used similarly, but they are different instruments.

Q. You might use one or another to get an answer to one or another different type of question?

A. Yes.

Q. And are those the only -- those three the only variations you were talking about when you asked about -- when you mentioned the different questions that could be asked?

A. So I mentioned DNA and RNA inputs, sample preparation, instrumentation and software. All of those

elements play into the question that's being asked.

Q. And what's the form of the report?

A. It varies, based on what a customer is attempting to do.

Q. Is the report spit out by the software?

A. Did you -- I'm sorry, can I ask a question? In this whole line of questioning are we talking about Illumina's products as a whole or specific for clinical use? What are we talking about right now?

Q. Paragraph 13 of your rebuttal declaration. I'm talking about what you are saying.

A. Okay.

Q. So is it ambiguous as to whether we are talking about all Illumina's products or just clinical diagnostics?

A. I wouldn't change any of my answers based on that.

Q. Could you answer my question?

A. I asked that question because I was looking for clarity; so, yes, it was ambiguous. That's why I asked that question.

Q. Is the data spit out by the software of the

Illumina instrument? Does the software provide the report?

A. Does software provide data in a report, yes.

Q. And what is the format of the report?

A. Software and report formats include flat files, PDF files, raw sequencing reads. There is any level of information available to the customer should they choose to have it.

Q. And then in the last sentence of paragraph 13 you say, "Similarly Meridian provides Illumigene assays that prepare a sample to be read by its Illumipro instruments"; right?

A. Yes.

Q. The customer of Illumipro does not get to choose the software; correct?

A. I don't know.

Q. You don't know?

A. I don't know.

Q. So you were willing to call it similar even though you don't even know that?

A. I don't say anything about software in that sentence.

Q. And do you know what the report format is from Illumipro reading an Illumigene assay?

A. I don't know, and I don't make a statement about the report.

Q. Do you know what kind of data is provided to the consumer when they use an Illumigene assay read by an Illumipro instrument?

A. I don't know.

Q. Your statement that Meridian's products act similarly is limited to what you have set forth in paragraph 13. It does not take into account any of those factors that you don't even know about.

A. My statement is drawing a parallel about sample prep and reading, and that's where the statement ends.

Q. Do you think that it's a useful expert opinion?

A. I don't -- I don't know.

Q. Why did you choose to give the opinion that they are similar?

MR. HORNE: Vague, mischaracterizes the declaration.

BY MR. HANKINSON:

Q. Pardon me. Maybe I'm mischaracterizing.

Did you give any opinion in here that the two are similar? Because I just asked about that, and your attorney said that I was mischaracterizing it.

A. I don't know if it's an opinion. I believe it to be true that in both Illumina and Illumigene assays DNA samples are prepared and read on an instrument for analysis, for molecular analysis. That is similar.

Q. Just that is similar. You're not giving an opinion that the products are similar?

A. The products are similar in that it's a sample preparation assay for molecular analysis that's read on an instrument.

Q. And only as to that?

MR. HORNE: Lacks foundation.

A. I don't -- I don't understand what you're excluding and saying "only."

BY MR. HANKINSON:

Q. The ability to choose the software, the ability to ask it different types of questions, the ability to look for different answers to those questions, and the same tasks, the output of the type of data and the format of the data, any opinion that you're expressing

in paragraph 13 that the products are similar is just not accounting for any of those other possible similarities or possible differences?

A. The variety --

Q. Because you don't know what Meridian's products aspects are with respect to those?

A. The variety of examples I gave you with choosing DNA and RNA, a variety of library prep, a variety of instrumentation and a variety of software represent a breadth of menu offered at Illumina that's capable of answering many different types of questions.

So depending on the question trying to be answered, a combination of those attributes would be selected by the customer for a specific answer. I'm not inferring that all of those apply to every single question.

Q. Nor are you giving any sort of opinion as to whether Meridian's products are similar or different with respect to those factors; correct?

A. I don't follow you. I don't know what you're saying.

Q. You listed a bunch of aspects of Illumina's

product offering.

A. Yes.

Q. You said that they are all part of the array of choices that Illumina provides to customers; right?

A. It's a product menu, yes.

Q. And you are not giving an opinion in paragraph 13 about whether Meridian's products branded as Illumigene and Illumipro have a similar or a different menu of options. It's just not there. You don't give that opinion.

A. I am giving an opinion. I'm saying it's similar.

Q. So you are saying it's similar.

A. I'm saying that the sample preparation -- a consumer of these products needs to prepare a sample and to read the result on a system. And the Illumigene assay and Illumipro instrument does that, as do Illumina's variety of library prep products and variety of instruments. The sample must be prepared and then read on an instrument for analysis. That is similar.

Q. That is the similar aspect upon which you are commenting; right?

A. Yes.

Q. And when you said you did not know what the format of the report for Meridian's products, that you did not know what type of data Meridian's products report and you did not know whether customers have an option of software when purchasing Meridian's products -- when you said all of that, it implied to me that you were not offering an opinion that Illumina's and Meridian's products were similar as to those aspects.

A. I don't know if they are similar to those aspects.

Q. So you are not offering an opinion one way or the other on that?

A. I'm not.

Q. And any opinion that you are offering in paragraph 13 as to the similarity is not taking into account those aspects; right? It is based only on what is in paragraph 13? Yes?

A. That's correct.

Q. In paragraph 15 you say, "In fact, LDTs are commonly used to diagnose patients. Often the same

clinicians in a lab are using both LDTs and IVDs. This is because the rapidly evolving needs at the diagnostics level vastly outpace the process of becoming an FDA-cleared or approved IVD.

"As an illustration, when a new disease or a new strain of a disease is discovered, the need to diagnose patients begins immediately, whereas the ability to receive FDA clearance or approval as an IVD lags behind. LDTs are critical to keep pace with medical needs."

You see that paragraph?

A. Yes.

Q. LDTs in a sense are on the cutting edge of clinical diagnostics. Do I have that right?

A. They can be.

Q. Sometimes LDTs lag behind?

A. They are able to meet the need at the cutting edge. They can also meet a need not at the cutting edge.

Q. The labs that provide LDTs, each one has to design its own laboratory-developed test; right?

A. Yes.

Q. And those laboratory-developed tests are subject to regulation; right?

A. Yes.

Q. CLIA certification?

A. Yes, as a requirement of the lab doing molecular analysis.

Q. And to do molecular analysis -- let me start again.

For a lab to perform a laboratory-developed test for the purpose of clinical diagnostics, it needs to be a high complexity CLIA lab; right?

A. It's -- that's not exclusive to LDT. A high complexity CLIA lab is not exclusive to LDTs. Molecular analysis in general needs to be done in a high complexity CLIA lab. There is one exception to that.

Q. So to do -- could you just read my last question back.

(Question was read)

A. Yes.

BY MR. HANKINSON:

Q. Could you please answer that question.

A. Yes.

Q. Thank you. There are other levels of complexity under CLIA; correct?

A. Yes.

Q. One of them is medium complexity?

A. Yes.

Q. There are more medium complexity CLIA labs than there are high complexity CLIA labs? Yes?

A. Yes.

Q. You do not offer in your declaration a quantification of how many medium complexity CLIA labs there are vis-a-vis high complexity CLIA labs; right?

A. No.

Q. No, you don't offer it?

A. No, I do not offer it.

Q. So in paragraph 15 when you say "often the same clinicians in a lab are using LTDs and IVDs," that is only in high complexity CLIA labs; right?

A. That's what I mean there, yes.

Q. And so never in medium complexity CLIA labs are the same clinicians using both LDTs and IVDs, correct, or else they would be violating their applicable regulations?

A. I don't know -- I don't know. If you qualify that by saying molecular LDTs, then I would agree.

Q. So when you say "often the same clinicians in a lab are using both LDTs and IVDs," you are speaking with respect to molecular LDTs only of CLIA high complexity laboratories; right?

A. Yes.

Q. And never is a laboratory that is merely a CLIA medium complexity laboratory doing molecular LDTs at the same time that they use IVDs?

A. Not to my knowledge.

Q. To your knowledge they are never doing that?

A. To my knowledge they are never doing that.

Q. Nowhere in your initial declaration or rebuttal declaration do you make the distinction between a CLIA high complexity laboratory and a CLIA medium complexity laboratory; correct?

A. I don't recall.

Q. Every time that you're talking about an LDT, you're talking about it being used in a CLIA high complexity laboratory; right?

A. Yes.

Q. And so every time you say something is often done in a lab through an LDT or can be done in a lab through an LDT or it's possible to do it in a lab through an LDT or it has been done in a lab through an LDT, those statements can only be describing CLIA high complexity labs with respect to molecular LDTs?

A. That is my understanding, yes.

Q. And those statements do not account for whatever part of the clinical diagnostics market is encompassed by laboratories that are merely CLIA medium complexity laboratories?

A. Yes. I agree.

Q. And nowhere in your initial declaration or your rebuttal declaration do you quantify what part of the market CLIA high complexity labs that do molecular LDTs constitute?

A. I do not.

Q. What is the difference between a CLIA high complexity lab and a CLIA medium complexity lab?

A. There's a difference in their certification.

Q. And a CLIA high complexity lab has a more stringent regulatory environment than a CLIA medium

complexity lab; right?

A. I don't -- I don't know if it's a more stringent regulatory environment. I don't know that.

Q. Are molecular diagnostic labs required to do their testing in a CLIA high complexity environment to control for a risk of a wrong result?

A. Yes.

Q. And is that environment more controlling for the risk of a wrong result because it is required to be a more controlled environment under the applicable regulations?

A. Yes. I believe that to be true.

Q. And that a more controlled environment under the regulation is brought about through various regulatory requirements that might include -- that do include increased training for employees; right?

A. I don't know the differences at that level.

Q. You don't know one way or the other?

A. I don't know.

Q. Do you know if the personnel who run CLIA high complexity laboratory environments are required to have more qualifications than persons who are permitted to

run CLIA medium complexity labs?

A. I don't know.

Q. You don't know one way or the other?

A. I don't know.

Q. Does a person who is using a laboratory-developed test in a CLIA high complexity lab need to be aware of the ingredients of the laboratory-developed tests to a high degree of certainty? And by ingredients I'm including components, instruments, and any other consumables that would be involved.

A. Yes.

Q. Do they have the relevant education and experience to know with that high degree of certainty exactly what is in the laboratory-developed test?

A. Yes.

Q. Do you think that they pay more or less attention to the sources of the components in the laboratory-developed tests than a person who is shopping for food at a grocery?

A. I don't know. I don't know.

Q. You don't have an opinion on that?

A. I -- I assume when you're going to a grocery store you want something specific so you're going to pick that specific thing. I don't understand the analogy.

Q. Are you aware of any buying situation in your ordinary life where there are multiple brands available for your choice and you don't necessarily go into that buying situation knowing exactly which one you're going to choose and you choose in the course of that buying experience?

MR. HORNE: Vague.

A. Yes.

BY MR. HANKINSON:

Q. And what is an example?

A. Yogurt.

Q. Yogurt. Do you have an opinion on whether a person who is performing a laboratory-developed test in a CLIA high complexity laboratory is more or less careful about the components and ingredients of laboratory-developed tests than a person who is selecting yogurt?

A. I think you're asking me if components can be

interchangeable like yogurt can be.

Q. I'm not.

A. Okay. I'm sorry, I don't understand what you're asking me.

Q. I'm asking about the level of care those two people are taking. Is one higher than the other?

MR. HORNE: Vague, incomplete hypothetical.

A. I don't know.

BY MR. HANKINSON:

Q. You don't have an opinion one way or the other on that?

A. No.

Q. You think it's entirely plausible that an individual selecting what kind of yogurt to buy is paying exactly the same amount of attention and care that a person in a high complexity CLIA lab environment is paying to the components and ingredients in a laboratory-developed test, despite one environment being highly regulated and requiring that they know exactly what the ingredients are to a high degree of certainty, as you told me earlier? You think the same applies to a decision as to yogurt?

MR. HORNE: Vague, incomplete hypothetical.

A. So -- I really am struggling to try to answer your question with this analogy with a yes or no question. It's not -- I don't have a yes or no answer.

BY MR. HANKINSON:

Q. What is your answer?

A. Let's make an analogy of --

Q. No. I'd like you to stick with my question.

A. I'm trying to find -- yogurt is a component, something you might buy. I may or may not care about what brand. Let's say I do. Let's say I always buy Dannon, every time I go to the store I buy Dannon yogurt. I don't even pay attention. I go and pick it up and buy it. At a point --

Q. I asked you to pick an example where you would go into a situation in your daily life --

A. Yes.

Q. -- where you did not have a specific brand in mind.

A. So you're saying interchangeable, I could change my mind? Is that what you're saying?

Q. I'm saying where you go into the buying

situation not having a particular brand in mind and there will be multiple brands to choose from, and you chose yogurt. Do you want to choose something else?

A. The -- I think you're trying to ask me if components can be interchangeable and not be --

Q. Please stop trying to guess at what I'm trying to get at, and listen to my questions. I'm not asking about the interchangeability of components.

A. Okay.

Q. Okay.

MR. HORNE: If you need clarification, ask.

THE WITNESS: Okay.

BY MR. HANKINSON:

Q. Do you want to select a different example of a common situation in your daily life where you go into the decision of whether to buy something without a specific brand in mind and there will be multiple brands to choose from?

A. No.

Q. So yogurt is an okay example?

A. Yes. That's fine.

Q. And we're going to talk about a person such as

yourself who is not addicted to Dannon and might buy various kinds of yogurt they don't know yet.

A. Okay, yes.

Q. There is a certain level of care that they will take in making that decision?

A. Yes.

Q. There's a certain level of care that a person using a molecular laboratory-developed test in a CLIA high complexity laboratory will take in selecting the components, ingredients of a laboratory-developed test. Yes?

A. Yes.

Q. I'm asking you to compare whether one level of care is higher than the other.

A. Yes. It's higher.

Q. Which one is higher?

A. An LDT is higher.

MR. HORNE: Let me know when we are close to break time.

MR. HANKINSON: We can take a break if this is good.

MR. HORNE: I was going to suggest we take a

lunch break. I have stuff being brought in; so...

MR. HANKINSON: Thank you, I appreciate that.

(Luncheon Recess was taken from 12:22 until 1:09 p.m.)

BY MR. HANKINSON:

Q. In your opinion do you think that the Trademark Trial and Appeal Board that will decide this case should view the consumers of Research Use Only labeled kits and the consumers of diagnostic products as the same market segment or different market segments?

MR. HORNE: Calls for legal conclusion, vague.

A. I believe that the same market segment uses both products, IVD-labeled and RUO-labeled.

BY MR. HANKINSON:

Q. For the same market segment, in your opinion?

A. Yes.

MR. HANKINSON: I'm going to mark Exhibit T.

(O'Grady Exhibit T was marked for identification)

BY MR. HANKINSON:

Q. Exhibit T is another news article produced in this litigation by Illumina, and it's dated January

15th, 2013.

Do you see that?

A. Yes.

Q. The title is Illumina CEO Jay Flatley on Diagnostics, the $1K Genome and China; right?

A. Yes.

Q. If you flip through the article, review it, there's a question and answer session between Xconomy, the publication, and Illumina's CEO Mr. Flatley. Right?

A. Yes, I see that.

Q. And we already established that you're not aware of any situation where Illumina has retracted or withdrawn any statements made by Mr. Flatley to the public; right?

A. I don't know of any.

Q. And if you could look at the page that's marked 5 of 8 in internal numbers or ILLUM-1566.

A. Okay.

Q. There is a question from Xconomy designated with an X about midway down the page that says "So there was a recent price increase for diagnostic customers, compared with standard academic research labs."

Do you see that question?

A. Yes.

Q. And Illumina's CEO Jay Flatley answered, "pricing for our RUO, Research Use Only, kit is different than for diagnostic customers. They are separate market segments. The diagnostic group does their pricing based on whatever the cost is of the infrastructure."

Did I read that correctly?

A. Yes.

Q. Do you think that Mr. Flatley was being misleading in any way when he said they are separate market segments?

A. I don't think the statement is entirely accurate.

Q. If you could look at Exhibit M, your rebuttal declaration, please turn to paragraph 37. In paragraph 37 through the end of your declaration, your rebuttal declaration, you discuss the registrations and applications of Illumina's trademarks at issue and Meridian's trademarks at issue. Right?

A. Yes.

Q. And you react to statements from Dr. Vecheslav Elagin regarding the recitations of products and services that are in those applications and registrations; right?

A. Yes.

Q. In paragraph 37 you say you disagree with Dr. Elagin, E-L-A-G-I-N. He says that the recitations in Illumina's applications are extremely vague, and you disagree. You say they are not vague; right?

A. Yes.

Q. You, in your rebuttal declaration, do not describe any particular educational background that you have that would give you a superior viewpoint in interpreting the recitations, do you?

A. No.

Q. You do not in your rebuttal declaration go into any of your professional experience that would give you a superior point of view regarding the meaning of Illumina's recitations; right?

A. No.

Q. And Illumina applied for registration of the name Illumina first in the year 2000; right?

A. I'm not clear on the exact dates of when that happened.

Q. That didn't make a difference to you in offering your interpretations of Illumina's applications and registrations?

A. To their vagueness, no.

Q. To any of it. It didn't matter to you when Illumina had applied with the recitation of goods and services that you are interpreting in this rebuttal declaration.

A. The date matters.

Q. You said you didn't know when the date is.

A. I know that it was before the -- Meridian's date. I know it was before that.

Q. But you don't know what year it was?

A. I don't recall.

Q. And you don't know how long before Meridian's application the first registrations of Illumina were filed?

A. I don't recall.

Q. You didn't state it in your rebuttal declaration?

A. No.

Q. And you didn't state it as a basis for any of the interpretations of those recitations in your rebuttal declaration?

A. No.

Q. So you interpreted Illumina's recitations from the perspective of Naomi O'Grady without regard to when they were filed. Is that accurate?

A. Yes.

Q. You did not attempt to interpret the recitations from the perspective of someone who is a consumer in any particular market as of the year 2000 specifically; is that correct?

A. I -- Yes, I believe that's correct.

Q. In paragraph 38 you discuss a recitation of goods in Meridian's Illumigene and Illumigene Molecular Simplified and design registrations; right?

A. Yes.

Q. And you note that Dr. Elagin says that one would interpret this to mean an amplification detection test for microbial, viral, or other disease-causing agent. That's sort of your setup. You're saying what

Dr. Elagin said; right?

A. Uh-huh.

Q. Then you say "I disagree with the statement"; right?

A. Yes.

Q. And you go on, "To the contrary, there are gastrointestinal, urinary, and respiratory diseases that are not caused by microbial, viral, or other disease-causing agent. These would include diseases that are inherited, have a genetic susceptibility and/or are acquired through somatic genetic mutations, such as cystic fibrosis, chronic obstructive pulmonary disease (COPD), stomach cancer, bladder cancer, colon cancer, and lung cancer."

That's your explanation for why you disagree; right?

A. Yes.

Q. Are you aware of a kit that would diagnose cystic fibrosis, chronic obstructive pulmonary disease, stomach cancer, bladder cancer, colon cancer, or lung cancer in 2008?

A. Yes.

Q. And by "kit" do we both understand it to be a complete set of the required components to diagnose that disease in and of itself?

A. Yes.

Q. What is that kit?

A. There are kits available for cystic fibrosis testing from a variety of providers.

Q. You said they are available. Were they available in 2008?

A. Yes.

Q. In paragraph 39 you take issue with Dr. Elagin's statement that one would recognize that nothing in Meridian's trademark registrations and applications refers to any good or service that would use random array technology; right?

A. Yes.

Q. And you say you disagree with respect to the Illumigene registrations; right?

A. Yes.

Q. And you explain that your reason for disagreeing is that molecular assays for use in disease testing and treatment of gastrointestinal, viral,

urinary, respiratory, and infectious diseases could be used with microarray or random array technology. That's your reason for disagreeing?

A. Yes.

Q. What molecular assays are you referring to that were on the market in 2008?

A. So the bead technology from Illumina, as well as -- I'm just going to focus on Illumina. Illumina's bead technology, the BeadXpress was capable of detecting all of these disease types. It's a random array technology.

In addition to that, the BeadChip platform was capable of detecting these molecular assays as well.

Q. In 2008 Illumina did not yet have IVD clearance for BeadXpress; correct?

A. No, they did not.

Q. Therefore, it would not be a diagnostic kit available in the market for clinical diagnostics; correct?

A. That's true.

Q. In paragraph 40 of your rebuttal declaration you take issue with Dr. Elagin's understanding of the

word "random" in Illumina's Registration Number 2471539; right?

A. Yes.

Q. You disagree with him?

A. Yes.

Q. So there is a difference of opinion about what that means?

A. Yes. I disagree with Dr. Elagin on that.

Q. And someone who is deciding what that means would need to choose between your interpretation and his interpretation; right?

A. Yes.

Q. So although you say that the recitation is not vague, that's because you have an opinion of what it means. But someone else does have a different opinion, and he also has credentials and experience that are related to this area of technology, and so it is susceptible to two different interpretations; right?

A. No, I disagree.

Q. You would like the Trademark Trial and Appeal Board to look at your interpretation as Naomi O'Grady as of the current date and decide not only that your

interpretation is the appropriate one to apply in this case but also that Dr. Elagin's interpretation is so wrong that there is not even a difference of opinion. That's what you think is the case?

MR. HORNE: With respect to random array?

A. I believe that he is not correct in his understanding of what random array means.

BY MR. HANKINSON:

Q. Could you answer my question.

A. I can't recall if -- the way it was phrased to answer yes or no.

MR. HANKINSON: Would you mind reading it back.

(Question was read)

A. Yes.

BY MR. HANKINSON:

Q. And you hold that opinion, even though Dr. Elagin has a longer professional career than you and more specifically applicable education in this field?

MR. HORNE: Lacks foundation, vague and argumentative.

A. The statements you just made about Dr. Elagin does not change my opinion.

BY MR. HANKINSON:

Q. In paragraph 41 of your rebuttal declaration you say that "Dr. Elagin also states that microarray technology is completely different from the Illumigene technology, which utilizes a single analyte amplification and detection by turbidimetry."

Do you see that?

A. Yes.

Q. Then you say, "With respect to the single analyte portion of this statement, there is nothing in the Illumigene recitations that limits the described goods to detection of a single analyte."

So that's a disagreement that you're stating?

A. Yes.

Q. You understand that the interpretation of a product and service recitation in a trademark matter is not like a patent claim where you interpret its breadth and anything that falls within it is within it and anything that falls out of it is out of it, but rather you're looking to see what it would mean to a relevant consumer at the time of the application.

Does that make sense?

MR. HORNE: Argumentative, calls for legal conclusion.

A. I don't have opinions about how patents are evaluated to react to your statement.

BY MR. HANKINSON:

Q. In interpreting the product and service recitations in the applications and registrations in this case, you make statements like this one:

That there is nothing in this recitation that would exclude in this example detection of a single analyte or in other examples that would exclude certain uses of products.

Do you understand what I'm saying?

A. Yes. I state that.

Q. And so your recitation interpretation is stating the broadest interpretation possible of the recitation, because you take issue each time someone says it means something by saying, well, it could include this or it could include that. So you're including in that recitation's meaning anything that it could include. Do you follow me?

MR. HORNE: Vague, argumentative, calls for

legal conclusion.

A. The words in the recitation don't include or exclude anything about the number of analytes in the assay.

BY MR. HANKINSON:

Q. And anything that technically could be included you are saying is part of the recitation?

A. I'm disagreeing with the statement that the -- I'm disagreeing with the statement of specifying it to mean single analyte, because it doesn't state that.

Q. It doesn't state it one way or the other is what you're saying?

A. It does not state it one way or the other.

Q. So you're saying when it doesn't state something one way or the other it should be interpreted to include anything that's not excluded?

MR. HORNE: Vague, calls for legal conclusion.

A. I'm just stating the fact that it doesn't say single analyte.

BY MR. HANKINSON:

Q. You didn't make any attempt to get inside the

head of a relevant consumer at the time of the application and interpret what the language would mean to them, but rather you're saying to me this does not specifically include -- exclude a single item analyte?

A. Yes.

Q. In paragraph -- later on in paragraph 41 you say, "With respect to the turbidimetry portion of his statement, there is nothing in the Illumigene recitations that limits the described goods to the use of turbidimetry." Right?

A. Yes.

Q. And that's the same issue. You're saying there is nothing in the recitation that limits it from your perspective, interpreting the words now; right?

A. Yes.

Q. In paragraph 41 Dr. Elagin makes reference to the Illumigene technology. Do you see that?

A. Yes.

Q. And then you take issue with his interpretation by saying that there is nothing in the Illumigene recitations that supports what he's saying; right?

A. Yes.

Q. So do you think that an interpretation of a recitation that depends upon an explanation of actual products in the market is flawed in some way?

MR. HORNE: Lacks foundation, argumentative, calls for legal conclusion, vague.

A. I don't understand your question.

BY MR. HANKINSON:

Q. Dr. Elagin was talking about the Illumigene technology; right?

A. Yes.

Q. And that has an existence in the world as a product; right?

A. Yes.

Q. He was making a statement about that and interpreting the recitations in the trademark applications and registrations?

MR. HORNE: Lacks foundation, argumentative.

A. I believe this is his interpretation.

BY MR. HANKINSON:

Q. Uh-huh. "Yes"?

A. Yes.

Q. And then you say, "Well, the recitations don't

limit it to what Dr. Elagin is saying about the technology"; right?

A. That's correct.

Q. And so then my question is so do you think there is something flawed about interpreting recitations like the ones that you're interpreting here by reference to what the marketed technology of a product is, or do you think that's an okay way to potentially interpret the recitations, is to look at the actual products?

MR. HORNE: Lacks foundation, calls for legal conclusion.

A. Yes. I believe that it's limiting to the interpretation to provide a specific example that generalizes.

BY MR. HANKINSON:

Q. It's limiting to the interpretation to provide a specific example that generalizes?

A. Meaning the only solution -- the Illumigene technology as described here is not the only solution that could be described by the recitation. It could also be a microarray or a multi-analyte assay.

Q. In paragraph 42 you take issue with

Dr. Elagin's statement that "Illumina-branded products are in a different field of endeavor with different consumers, consumers who are looking not for ready-made IVD tests and locked IVD software on readers of those tests, but rather for open platform research equipment that customers can tweak, certainly RUO products, not IVD products."

Do you see that?

A. Yes.

Q. You say, "This statement is incorrect because Illumina-branded products are not only bought by consumers looking for open platform research equipment, rather Illumina-branded products are also purchased by labs that develop diagnostic tests." Right?

A. Yes.

Q. But a lab that develops a diagnostic test develops that test itself; right?

A. Yes.

Q. It has to take responsibility for the development and validation of that test; right?

A. Yes.

Q. And the validation of the equipment and

components that are used in the laboratory-developed test; right?

A. Yes.

Q. And Illumina is not permitted to market its RUO-labeled products for specific purposes in diagnosing disease in humans through those laboratory-developed tests. It has to leave that to the laboratory; right?

A. Yes.

Q. So a laboratory that's buying the Illumina-branded products that you're talking about for developing diagnostic tests would need a platform that they can use to make a test; right?

A. Yes.

Q. They need to tweak it?

MR. HORNE: Lacks foundation, argumentative.

BY MR. HANKINSON:

Q. Let me state it this way. It's not a kit. It's a platform.

A. Yes.

Q. Then you say, "And, as explained in my and Ms. Possemato's original declarations in this matter, Illumina sells FDA-cleared IVD products."

Now, that's a statement as of the current date; right?

A. Yes.

Q. Not as of the date of the applications and recitations for the Illumina brand in the year 2000?

A. Yes. Illumina did not have approval in 2000.

Q. Illumina did not have FDA approval until September 2009 for any product; correct?

A. Yes. That's right.

Q. Do you know that that is after Meridian's application for the Illumigene brand?

A. I don't know the exact date of the Illumigene brand.

Q. You don't know one way or the other?

A. No.

Q. And so that did not matter to you in interpreting the recitations?

A. No.

Q. In paragraph 43 of your rebuttal declaration you say, "As explained above, since at least 2007 Illumina's products have been selected by CLIA certified labs for use in LDTs."

Did you use the verb "selected" instead of "purchased" because they can't legally be marketed for that purpose, but they can legally be selected after purchase to be used in LDTs?

A. No.

Q. Why didn't you use the term "purchased"?

A. No particular reason.

Q. But in 2007 those products could not have been marketed by Illumina for a diagnostic purpose; right?

A. Yes.

Q. Then you say, "Consumers that create LDTs are often also purchasers of IVD products"; right?

A. Yes.

Q. You do not, in this paragraph or elsewhere in your rebuttal declaration, provide the total number of purchasers in the market that you are discussing, do you?

A. I do not.

Q. And you do not anywhere in this paragraph or anywhere else in your rebuttal declaration provide the number of consumers that both create LDTs and purchase IVD products?

A. No, I do not.

Q. So this is a use of the word "often" that's not supported by any data through which you would have a percentage. It's susceptible to interpretation what "often" means in this sentence?

A. Yes.

Q. In paragraph 44 you state, "For this same reason, Dr. Elagin is incorrect when he states in paragraph 14 that the random array technology described in this recitation implies such open platform research equipment that is used by consumers, separate and distinct from the ready-made kits identified in Meridian's Illumigene recitations. Nothing in the recitation in Illumina's Registration Number 2471539 says that the developed goods would only be used for research."

Do you see that?

A. Yes.

Q. So in order for the meaning of that recitation to exclude -- let me start again.

It's not that the description that you're discussing, the recitation that you're discussing says

that the products being described would be used outside of research. Rather, you're saying it doesn't say that they wouldn't be used outside of research. Do I have that right?

A. I'm having a hard time following the different negatives counteracting each other in order to understand your statement.

Q. You say nothing in the recitation in Illumina's Registration Number 2471539 says that the developed goods would only be used for research; right?

A. Yes. That's what I say.

Q. And so before you would interpret that recitation to be limited to research, you would be looking for a specific statement that this can only be used in research; is that right?

MR. HORNE: Mischaracterizes testimony, argumentative.

A. I don't understand what you're saying.

BY MR. HANKINSON:

Q. In the last two sentences of paragraph 44 you say, "In addition, nothing in the recitation in Illumina's Registration Number 2471539 says that the

recitation would only be used for open platform use. Instead, the recitation could be for targeted applications."

Do you see that?

A. Yes.

Q. What did you mean by "targeted applications"?

A. That the technology could be applied for a specific purpose to answer a question.

Q. What about that recitation made you think that it meant targeted applications?

A. I'm just stating that it doesn't -- it doesn't limit it to open platform use.

Q. You're not giving the opinion that it means targeted applications. You're giving an opinion that it doesn't exclude them?

MR. HORNE: Vague, argumentative.

A. I'm saying it does not include or exclude either. It doesn't state specifically open platform use.

BY MR. HANKINSON:

Q. So it could be interpreted to be either?

A. It could be either.

Q. And yet you say that it's not vague?

MR. HORNE: Argumentative.

A. Yes, I say that.

BY MR. HANKINSON:

Q. In paragraph 45 you take issue with Dr. Elagin's interpretation of Illumina's Registration Number 2756703, and you set out the product recitation --

A. Uh-huh, yes.

Q. -- from that registration.

And then you say that in paragraph 16 Dr. Elagin states that that recitation describes types of equipment that are used in the scientific research.

And you say, "To the extent Dr. Elagin is suggesting that the recitation describes types of equipment that are only used in scientific research, he is wrong. To the contrary, the goods described in this recitation could be purchased by a diagnostic laboratory for use in LDTs and have been purchased extensively by customers who develop LDTs." Right?

A. Yes.

Q. If you were trying to write a product

description that would inform the Patent and Trademark Office that you wanted to market diagnostic products and products that can be purchased by a diagnostic laboratory for use in laboratory-developed tests, don't you think it would be a good idea to say so?

MR. HORNE: Calls for legal conclusion, argumentative.

A. I don't have an opinion on that.

BY MR. HANKINSON:

Q. Your interpretation is that this language from the Registration 2756703 could include this use of such equipment by a diagnostic laboratory for use in a laboratory-developed test; right?

MR. HORNE: Mischaracterizes testimony, vague.

A. The description could describe a product that would be used for that purpose, yes.

BY MR. HANKINSON:

Q. And you didn't know when this was written when you wrote your rebuttal declaration?

A. I know --

Q. It was before Meridian --

A. I know loosely the time frame. The specific

years I couldn't recite for you.

Q. Well, what's loosely the time frame?

A. In the 2000 plus time frame. If it was precisely '99 or 2000, I don't know.

Q. You're not just saying that because I already said that today?

A. No.

Q. So in 2000 through 2006 are you aware of products branded Illumina that were used in diagnostic laboratories?

A. No, I'm not aware of that.

Q. And do you know that between 2000 and 2006 Illumina told the Patent and Trademark Office that it had used the trademarks as described in the registrations?

MR. HORNE: Lacks foundation.

A. I started at Illumina in 2007. I don't know about -- anything about that.

BY MR. HANKINSON:

Q. So none of that transpiring had any impact on your interpretation of the meanings of the recitations in your rebuttal declaration?

A. No.

MR. HANKINSON: I'm going to mark Exhibit U. Unfortunately -- I apologize -- I only have this clean copy. I'm going to have to impose on you to share, or we could copy it if you want.

MR. HORNE: We'll do our best to share and see how it goes.

(O'Grady Exhibit U was marked for identification)

BY MR. HANKINSON:

Q. I'll talk about it while you look, if you don't mind.

This is -- Exhibit U is a chart that my office made of the product and service recitations for Illumina's and Meridian's applications and registrations that are at issue in this case.

So you'll see on the left-hand side of the chart there is Illumina marks that include Illumina, Illumina, Illumina, IlluminaDX and IlluminaDX and on the right-hand side of the chart there are Meridian marks Illumipro, Illumipro-10, Illumigene, and Illumigene Molecular Simplified & design.

This puts in one place the recitations from all those different registrations and applications. Do you understand?

A. Yes.

Q. So I want to ask you about the recitations, and we can use Exhibit U so that we see the actual language that's in them.

A. Okay.

Q. If you look at Illumina's Registration Number 2471539, after class 40 there is a recitation. Are you with me?

A. Yes.

Q. And it says, "Developing to the order and specification of others, biological and/or chemical sensing systems which use random array technology to identify inorganic and organic molecules, compounds, and substances." Okay?

A. Yes.

Q. The words "to the order and specification of others," do you understand that to mean someone else is directing Illumina in, you know, how to develop the biological and/or chemical sensing system?

A. No.

Q. Someone else has to give the order and specification; right?

A. Yes.

Q. And then this is a service of developing that biological and/or chemical sensing system to the order and specification of that other party; right?

A. Yes.

Q. And the biological and/or chemical sensing systems described in this recitation use random array technology; right?

A. Yes.

Q. If you'd look in the four Meridian marks, Illumipro and Illumipro-10 both start by saying diagnostic machine; right?

A. Yes.

Q. And Illumigene and Illumigene Molecular Simplified & design each start with diagnostic kits; right?

A. Yes.

Q. So these are products, machines and kits that are being sold; right?

A. I assume they are being sold, yes.

Q. They don't say that it's a service of developing something to the order and specification of others; right?

A. The words on the page do not say that.

Q. And there are other words that you want to refer to, other than those on the page?

A. No. I'm telling you what it literally says. It does not say that.

Q. Right. And there is no such service being offered, in other words?

A. I don't know that to be true or not.

Q. You can't interpret that language, whether or not it does or does not?

A. Yes. That's true. I cannot do that.

MR. HORNE: Object to the last question being vague.

BY MR. HANKINSON:

Q. That's interesting. So you can't interpret whether the product recitations in these four include a service of developing to the order and specification of others particular sensing systems? You can't even say

one way or the other?

A. I'm sorry, which one specifically?

Q. These four.

A. The four. The fourth one on here that says Illumina Molecular Simplified & design, I -- it could imply that they are designing something for someone. It doesn't specify if it is or not.

Q. It doesn't say they are designing something, does it?

A. It just says design.

Q. Where does it say design?

A. In the title.

Q. Oh, you're referring to "& design"?

A. Yeah.

Q. I can represent to you that "& design" means like a figure, an icon or a design that goes along with the words in the trademark. So exclude that --

A. Okay.

Q. -- and look at the recitation.

A. It doesn't say anything about whether there is any sort of custom capability or not. It doesn't say anything about that.

Q. Well, it doesn't say that they are selling custom design, does it?

A. No, it does not say that.

Q. Whereas Illumina's Registration 2471539 says they are selling the developing to the order and specification of others these sensing systems; right?

A. Yes.

Q. Look at Illumina's Registration Number 2632507.

A. Yes.

Q. Well, actually, by the way, looking at that recitation, do you have any understanding of what that referred to in the year 2000 to 2003 that Illumina actually made?

MR. HORNE: Vague, lacks foundation.

A. I am -- I don't know.

BY MR. HANKINSON:

Q. Are you aware of, like, custom-installed genetic sequencing equipment that cost $500,000 or more made in that time frame by Illumina?

A. I'm not aware.

Q. And so that didn't enter at all into your interpretation of Illumina's recitations in your

rebuttal declaration?

A. No.

Q. If you look at Illumina Registration Number 2632507, there is two recitations. I want to take them separately.

The first one starts with Class 1.

A. Okay.

Q. Do you see it?

A. Yes.

Q. It says, "chemicals, namely reagents, for scientific or medical research use for analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons" -- that's D-A-L-T-O-N-S -- "sequencing DNA, genotyping, gene expression, profiling, and high throughput screening." Right?

A. Yes.

Q. And so the product in this recitation is reagents for scientific or medical research use, and then it specifies the uses; right?

A. Yes.

Q. Then if you look at Class 42 under the same Registration Number, it says "Scientific and medical

research, namely analysis of cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing DNA, genotyping, gene expression profiling, and high throughput screening." Right?

A. Yes.

Q. And so the service here is scientific and medical research of the type described; right?

A. The word "service," I don't understand what you mean by that.

Q. Is the product or service that's being described by the second recitation here after Class 42, scientific and medical research, that's what's being sold and that's more specifically described after "namely"?

A. The statement specifies the segment there as scientific and medical research. I don't think you can actually sell research. It doesn't make sense. What you just said didn't make sense to me.

Q. So if Illumina in its Registration 2632507 told the Patent and Trademark Office that it was selling scientific and medical research of the type described after the word "namely," that would not make sense?

MR. HORNE: Lacks foundation, calls for legal conclusion.

A. I interpret that to mean the application area.

BY MR. HANKINSON:

Q. So whatever is being sold here is being sold to the application area of scientific and medical research? That's your interpretation?

A. That's what I understand for that class.

Q. Okay. If you look back at the four Meridian marks in the column on the right -- again, the Illumipro and Illumipro-10 recitations begin with diagnostic machine; and Illumigene and Illumigene Molecular Simplified & design applications, the recitation begins with "diagnostic kits"; right?

A. Yes.

Q. They do not purport to describe products for scientific or medical research use, right, but rather diagnoses?

A. That's what it looks like, yes.

Q. And they do not purport to describe products or services being sold to the -- what did you call it -- the application area of scientific and medical

research, but, rather, diagnoses?

A. I'm sorry, can you ask the question again?

Q. What did you call scientific and medical research after Class 42 in Registration Number 2632507?

A. It looks like the segment where the technology is being applied, scientific and medical research.

Q. Okay.

A. It's defining an area and showing a type of methodology and technology after it.

Q. Within that area?

A. Within that area.

Q. And the Illumipro, Illumipro-10, Illumigene, and Illumigene Molecular Simplified & design product recitations on the right-hand side of the chart do not specify that segment or application area?

A. No. It does not specify that.

Q. Rather, it specifies that these are diagnostic machines and diagnostic kits; right?

A. Yes. That's what it says.

Q. If you look at Illumina Registration Number 2756703 --

MR. HORNE: I don't know how long you'll be on

this one, but we could certainly use a break pretty soon.

MR. HANKINSON: It shouldn't be too much longer.

MR. HORNE: Okay.

BY MR. HANKINSON:

Q. Actually if you could look at Registration Number 2632507 for a little bit more, that has the Class 1 and the Class 42?

A. Yeah.

Q. Each of those -- well, the first says scientific or medical research use; right?

A. I'm sorry, can you tell me again where I'm looking?

Q. Yeah. Class 1 --

A. Yeah.

Q. -- in Registration 2632507 under Illumina, it uses the phrase for scientific "or" medical research use; right?

A. Yes.

Q. And the second recitation there says scientific "and" medical research use or research; right?

A. Yes.

Q. And so "scientific" and "medical" are two different words being used in each of these recitations; right?

A. Yes.

Q. "Medical" being more specifically in the field of medicine and "scientific" being, you know, research and science. They are two different things; right?

A. Yes.

Q. Now, if you look at Registration Number 2756703 for the trademark Illumina, after Class 9 it begins "scientific equipment and instruments"; right?

A. Yes.

Q. And so if the same person is describing goods as the person who is, you know, describing -- let me start that over again.

So "scientific" there, as opposed to "medical," means that this equipment and instrument is to be used for scientific purposes; right?

MR. HORNE: Vague.

A. I don't know.

////////

BY MR. HANKINSON:

Q. But if "scientific" and "medical" have two different meanings so they are both used separately in Illumina's registrations from that time period, one would assume that "scientific" means something different from "medical," or else they wouldn't have used two different words?

MR. HORNE: Lacks foundation, argumentative, calls for legal conclusion.

A. I don't know.

BY MR. HANKINSON:

Q. You can't say from looking at this recitation?

A. Can't say what?

Q. You said you don't know. You can't say what "scientific" means is what you're saying?

MR. HORNE: Argumentative, mischaracterizes testimony.

BY MR. HANKINSON:

Q. So I've mischaracterized it. So you must be able to tell me what "scientific" means.

A. For me the statement "scientific equipment and instruments" is defining a broader spectrum of use.

It's not specifying research or medical. It's just talking about science. Both medicine and research use scientific equipment. I don't exclude one or the other, based on what it says.

Q. But that can't be what Illumina meant in 2000, because they said in Registration Number 2632507 "scientific and medical research" under Class 42. So if what you're saying it meant were true, they would not have said "and medical."

MR. HORNE: Argumentative, lacks foundation.

BY MR. HANKINSON:

Q. Scientific research would have included medical?

MR. HORNE: Done? Argumentative, lacks foundation.

BY MR. HANKINSON:

Q. Right? Sorry.

MR. HORNE: Argumentative, lacks foundation and calls for legal conclusion. Try to interrupt that.

A. I don't know.

BY MR. HANKINSON:

Q. Well, follow with me here. Illumina in the

year 2000 submitted each of these three registrations; and Registration Number 2632507 in its second recitation, the one that follows Class 42, says "scientific and medical research."

You're with me there; right?

A. Yes.

Q. If scientific meant both medical and other science, then there would be no reason to put "and medical." It would just say scientific research, right, because that would include medical; right?

MR. HORNE: Lacks foundation, calls for legal conclusion.

A. I don't know what was intended there.

BY MR. HANKINSON:

Q. So you're trying to look at these recitations with your own interpretation as of the current date, and the use of scientific and medical in Registration 2632507 just doesn't square with your understanding of what "scientific" means? Is that what you're saying?

MR. HORNE: Mischaracterizes the testimony, argumentative.

A. I'm sorry, I forgot what you asked me.

MR. HANKINSON: Would you mind reading it back. Thank you.

(Question was read)

A. No.

BY MR. HANKINSON:

Q. So look at the phrase in Registration Number 2632507 after Class 42 --

A. Yes.

Q. -- where it says "scientific and medical research."

A. Yes.

Q. You have told me that your understanding of the word "scientific" includes medical and other stuff. Do you still --

A. Yes.

Q. -- believe that?

A. Yes.

Q. Okay. Someone at Illumina -- or excuse me. Illumina submitted this registration to the Patent and Trademark Office in 2000. Okay?

A. Okay.

Q. Illumina said "scientific and medical

research."

A. Okay. Yes.

Q. So the -- so Illumina, in making that submission, used "medical" as a distinct word that was added onto "scientific," scientific and medical research. Right?

A. Yes.

Q. So if Illumina in 2000 had the same view as you do today of the word "scientific" --

A. Yes.

Q. -- then it would not have used that phrase. It would have just said "scientific research"; right?

MR. HORNE: Lacks foundation, argumentative, calls for legal conclusion.

BY MR. HANKINSON:

Q. Because adding "and medical" would have been redundant?

MR. HORNE: Same objections.

A. I don't know what decisions were made and why at that time.

BY MR. HANKINSON:

Q. You in your rebuttal declaration are telling

the Trademark Trial and Appeal Board what Illumina's product and service recitations mean, and you're disagreeing with Dr. Elagin's interpretations; right?

A. Yes.

Q. So you in your rebuttal declaration said "I have personal knowledge of the matters set forth herein and if called upon to testify I could and would competently testify thereto." Right?

A. Yes.

Q. So when you're interpreting Illumina's product and service recitations, I'm asking you to testify from your personal knowledge about those. Can we agree that you'll do that?

A. Yes.

Q. So when you look at Registration Number 2632507 after Class 42, Illumina in its registration used the phrase "scientific and medical research"; right?

A. Yes.

Q. And if "scientific" included "medical," then the phrase "and medical" would have been redundant; right?

MR. HORNE: Lacks foundation, argumentative,

calls for legal conclusion.

A. I don't have a different answer for you.

BY MR. HANKINSON:

Q. You haven't given me an answer. Would "and medical" be redundant if "scientific" meant what you're saying, that it included "medical"?

MR. HORNE: Same objections.

A. Not necessarily.

BY MR. HANKINSON:

Q. Does the word "scientific" -- so you're saying "and medical" would not necessarily be redundant?

A. It could be qualifying or clarifying to call out a certain area specifically in addition to the broader area.

Q. That's a good point. So you can use "and" in order to clarify with the word after the "and" what the things prior to the "and" were meant to refer to; is that what you're saying?

A. Yeah.

Q. So if you look at Illumigene's Registration Number 3868081, it says "diagnostic kits consisting of molecular assays for use in disease testing and

treatment of gastrointestinal, viral, urinary, respiratory, and infectious diseases."

Do you see that?

A. Yes.

Q. And you have said in your rebuttal declaration that because some of the things prior to the "and" -- gastrointestinal, viral, urinary, and respiratory -- can include infectious diseases or inherited diseases that this must be broad enough to include both kinds. That's your opinion in your rebuttal declaration; right?

A. Yes.

Q. But if a word following "and" can be used to clarify in a limiting way what comes before it, then infectious diseases would be interpreted to clarify in a limiting way what came before it, and it would be limited to infectious diseases; right?

A. I don't think I've said previously that use of the word "and" is necessarily limiting to apply it to other phrases.

Q. You said that it could be.

A. I said that it could be clarifying. I didn't say "limiting." I didn't say "limiting."

Q. Clarifying --

A. Clarifying.

Q. -- what the prior terms before the "and" meant.

A. It could be.

Q. Okay. And what you're doing, then, is interpreting that one way in Illumina's Registration 2632507, in a different way in Illumigene's Registration Number 3868081.

MR. HORNE: Argumentative.

A. I don't think you asked me a question.

BY MR. HANKINSON:

Q. Right?

A. I don't know.

Q. You're not sure?

A. I'm not sure.

Q. But your opinion is that these product and service recitations are not vague?

A. Yes. That's my opinion.

Q. So they are susceptible of only your interpretation and not others?

A. No.

Q. Well, "vague" means they are susceptible to

multiple interpretations; right?

MR. HORNE: Argumentative, lacks foundation.

A. I don't know -- I don't know.

BY MR. HANKINSON:

Q. Do you have a working definition of the word "vague" that you use?

A. Unclear, not specific.

Q. And you think that's different from susceptible to multiple interpretations?

A. No.

Q. So it's pretty much the same gist?

A. Yes.

Q. Are you now saying that the product recitations and service recitations in Illumina's registrations may be susceptible to multiple interpretations?

A. It seems clear to me what's stated here.

Q. In Illumina's product and service recitations. That's what seems clear to you?

A. Yes.

Q. So it's clear to you that in Registration Number 2632507 under Class 42 the phrase "scientific and medical research" -- you think it's clear that "and

medical" clarifies what scientific means, as opposed to being a list of two separate things? That's clear to you?

MR. HORNE: Mischaracterizes the testimony.

BY MR. HANKINSON:

Q. This one is really just yes or no.

A. Yes, it's clear to me.

Q. Okay. And then when you look at Illumigene's Registration Number 3868081 and there are words before an "and" and after an "and," it's not clear to you that what comes after the "and," infectious diseases, clarifies what came before it? That you just don't know?

A. It appears to be a list to me of disease states. It does not appear to state that all of those are infectious disease tests.

Q. And so you're interpreting the use of the word "and" in a different way for that recitation than for the recitation in Illumina Registration Number 2632507?

A. Yes.

Q. All right. Now look at Class 1 under Registration Number 2632507. Are you with me?

A. Yes.

Q. It says, "Chemicals, namely reagents, for scientific or medical research use."

A. Okay.

Q. So here in 2000 Illumina is submitting to the Patent and Trademark Office that these reagents are for scientific "or" medical research use; right?

A. Yes.

Q. And Illumina -- if "scientific" included "medical," wouldn't the phrase "or medical" be redundant in this product recitation?

MR. HORNE: Argumentative, lacks foundation, calls for legal conclusion.

A. I don't know.

BY MR. HANKINSON:

Q. Ms. O'Grady --

A. Yes.

Q. -- you said in your rebuttal declaration that you can testify from your personal knowledge competently on everything that's in your rebuttal declaration; right?

A. Yes.

Q. And you interpreted the product and service recitations for Illumina's registrations and applications and Illumigene and Illumipro applications in your rebuttal declaration; right?

MR. HORNE: Vague, lacks foundation.

A. Can you restate what you just said?

BY MR. HANKINSON:

Q. Sure. You discuss at length in your rebuttal declaration the product and service recitations in the registrations and applications at issue in this case.

A. Yes.

MR. HORNE: Vague, lacks foundation.

BY MR. HANKINSON:

Q. You also said that you disagree with Dr. Elagin when he says that Illumina's recitations are vague; right?

A. Yes.

Q. Okay. So now what I'm asking you, in Registration Number 2632507 wouldn't "or medical" be redundant if scientific included medical; and you answer me "I don't know." That does not square with what you're saying in your rebuttal declaration.

MR. HORNE: Lacks foundation.

BY MR. HANKINSON:

Q. Is it clear to you what that means, or do you not know what it means?

A. I understand what is meant by scientific and medical research.

I don't -- I don't know why there is an "or" and then an "and." I don't know.

Q. So let's now start from the premise that Illumina meant something specific by its product and service recitations. Okay? Can we accept that premise for the following line of questioning?

MR. HORNE: Lacks foundation, vague.

A. I'm sorry, you're asking me to assume...

BY MR. HANKINSON:

Q. Let's assume they meant to use these words on purpose. Okay?

A. Okay.

Q. And Illumina meant in Registration 2632507 to use the phrase "scientific or medical research," and they meant something by that; and if Illumina meant to use in that same registration the phrase "scientific and

medical research" and Illumina meant something by that, then Illumina was not using scientific to include medical. Illumina meant something different by "medical"; right?

MR. HORNE: Argumentative, lacks foundation, calls for legal conclusion.

A. To say one or the other would imply something different.

BY MR. HANKINSON:

Q. So if we assume they were doing it on purpose, then it meant something different to Illumina at that time, right, between "scientific" and "medical"?

MR. HORNE: Same objections.

A. I don't know what it meant at the time.

BY MR. HANKINSON:

Q. But you would agree that if they meant to use these words, "scientific" meant something different to Illumina than "medical"?

MR. HORNE: Lacks foundation.

BY MR. HANKINSON:

Q. There is no other interpretation of this; right?

MR. HORNE: Argumentative, lacks foundation, calls for legal conclusion.

A. I don't -- I don't know.

BY MR. HANKINSON:

Q. Can you provide any reason that Illumina would use the phrase "scientific or medical" and separately the phrase "scientific and medical" in its Registration 2632507, where it wouldn't be meant as scientific and medical meaning different things?

A. No.

Q. In Illumina Registration Number 2756703 after Class 9 it begins, "Scientific equipment and instruments"; correct?

A. Yes.

Q. And so if Illumina is submitting all three of these applications in the year 2000, in fact over the same summer of 2000, then Illumina meant when it said "scientific" in Registration 2756703 something different from "medical." That follows logically; right?

MR. HORNE: Lacks foundation, argumentative.

A. Not necessarily. There is nothing for me when I read that statement that specifies a market segment.

It just says scientific equipment and instruments. It doesn't say if it's for scientific or medical research. It doesn't qualify either way. It just says science.

MR. HORNE: I don't want to interrupt the line of questioning, but we've been going an hour and a half, hour and 35 minutes. If we could take a break, it would be good.

MR. HANKINSON: May I finish the line of questioning?

MR. HORNE: Depends how long it's going to be, which is why I asked 15 or 20 minutes ago, but I'm not going to interrupt you. Soon, please.

BY MR. HANKINSON:

Q. You understand when a company submits an application for a trademark it should try to be accurate and complete with the Patent and Trademark Office?

A. I would assume that's the case.

Q. And part of being clear and accurate in language is using language consistently; right?

A. Yes.

Q. And it sounds to me like what you're saying is that Illumina was using language inconsistently between

Registration Number 2632507 where "scientific" and "medical" meant something different from each other, if they meant anything at all, and Registration Number 2756703 where Illumina chose the word "scientific" and did not put "and medical" or "or medical."

Do you think that Illumina was using that language inconsistently between the two registrations that were made in the same summer of the year 2000?

A. No.

MR. HORNE: Argumentative, lacks foundation.

MR. HANKINSON: That's it.

(Recess was taken from 2:48 until 3:03 p.m.)

BY MR. HANKINSON:

Q. Could you turn in Exhibit M, your rebuttal declaration, to paragraph 31; and on the next page, page 8, you say "Dr. Stephen Young is the scientific director of infectious disease at TriCore Reference Laboratories and a professor in the department of pathology at the University of New Mexico."

That's the Dr. Stephen Young we were discussing earlier; right?

A. Yes.

Q. You go on to say, "He has purchased an Illumina BeadArray Reader specifically for cytogenetics use"; right?

A. Yes.

Q. Is that true?

A. No.

Q. What steps have you taken to withdraw that statement from the Trademark Trial and Appeal Board or correct it?

A. I am not sure how to answer that question without disclosing conversations with the lawyers at Illumina.

Q. I didn't hear a privilege objection.

MR. HORNE: Well, I'll make one then.

Don't answer the question to the extent it requires you to divulge attorney/client communications.

BY MR. HANKINSON:

Q. So, Miss O'Grady, have you taken any step to withdraw or correct this untrue statement that's in your rebuttal declaration from or to the Trademark Trial and Appeal Board, other than confidential communications with your attorneys that you cannot disclose to me?

A. No.

Q. Do you understand that when you sign a declaration like this it's -- you know, it says explicitly in the passage right before the signature block that it's subject to the penalties for perjury?

A. Yes.

Q. So you understand that you ought to take some step to correct this; right?

A. Yes.

Q. But you have not done so yet?

MR. HORNE: Lacks foundation, calls for attorney/client privileged communications.

A. No.

BY MR. HANKINSON:

Q. Do you also understand that companies that have applications and registrations before the Patent and Trademark Office have a duty to be candid with that office?

A. I assume that to be true.

Q. And so, in any event, Dr. Stephen Young did not purchase an Illumina BeadArray Reader; right?

A. That's true.

Q. Is it my understanding that he or his lab considered purchasing one?

A. Yes.

Q. And that that would be a more accurate statement?

A. Yes.

Q. Do I further understand correctly that the reason that you made this untrue statement in your rebuttal declaration is that you misinterpreted the Illumina documents?

A. The customer records, yes. I misunderstood what they said.

Q. So the answer to my question is "yes"?

A. Yes.

Q. Now, this statement that Dr. Young has purchased an Illumina BeadArray Reader specifically for cytogenetics use, it doesn't cite a document, does it?

A. No.

Q. And in paragraph 1 of your rebuttal declaration you stated, "I have personal knowledge of the matters set forth herein, and if called upon to testify I could and would competently testify thereto."

Is that accurate?

A. Yes.

Q. Did you understand that when you signed this declaration?

A. Yes.

Q. But when you said he has purchased an Illumina BeadArray Reader specifically for cytogenetics use, not only is that untrue, but it wasn't based on your personal knowledge; it was based on your misinterpretation of a document that you did not cite.

Do I have all that accurate?

A. No.

MR. HORNE: Argumentative.

BY MR. HANKINSON:

Q. Do you cite a document here?

A. I do not cite a document there.

Q. Was your untrue statement based on a misinterpretation of an Illumina customer record?

A. In -- in addition to that, I personally visited the lab when those conversations were happening; so I did not remember correctly what occurred at that point of time when this opportunity was under discussion.

MR. HANKINSON: I'm going to mark Exhibit V.

(O'Grady Exhibit V was marked for identification)

BY MR. HANKINSON:

Q. Take a moment and look at Exhibit V and just tell me if you've seen it before.

A. Yes.

Q. In the first -- Well, first of all, this is an email from Illumina's attorney, Brian Horne, to me; right?

A. Yes.

Q. It's from earlier this month?

A. Yes.

Q. Between the time that you signed your declaration and the time that I received this email on May 4th, Illumina's attorneys became aware that Meridian's attorneys intended to take a deposition of Dr. Young; right?

A. I'm not sure I can answer that question without divulging information that was discussed with Illumina attorneys.

MR. HORNE: Instruct you not to answer to the

extent you're going to reveal attorney/client communications.

BY MR. HANKINSON:

Q. Did you become aware at some point in time that Meridian's attorneys intended to take a deposition of Dr. Young?

A. Yes.

Q. Did you only after becoming aware that Meridian's attorneys were going to take a deposition of Dr. Young communicate with your attorneys about this inaccurate statement in your rebuttal declaration?

A. I realized I was wrong after that point.

Q. And in Exhibit V, in the first sentence it states, "In reviewing her rebuttal declaration, Ms. O'Grady realized that she had misinterpreted Illumina's records as they relate to a statement she made in paragraph 31 about Dr. Young, more specifically her statement that Dr. Young has purchased an Illumina BeadArray Reader is incorrect."

Do you see that?

A. Yes.

Q. And so Mr. Horne told me that you realized in

reviewing your rebuttal declaration that you had misinterpreted Illumina's records; right?

A. That's correct.

Q. And that that led you to understand -- or excuse me -- that that misinterpretation of Illumina's records had led to your statement that he had purchased a BeadArray Reader; right?

A. That's right.

Q. Now you're telling me that it was not your misinterpretation of Illumina's records that led for you to make this untrue statement in your rebuttal declaration?

A. No. That is the reason I made that statement. I misinterpreted what was in the customer record.

Q. So by not identifying that customer record, had you not realized this mistake, Meridian and its attorneys would have had no way to check whether you were interpreting that customer record accurately or inaccurately, because we wouldn't know that this statement is based on a record, would we?

MR. HORNE: Argumentative, lacks foundation.

A. I don't know how you would know that.

BY MR. HANKINSON:

Q. It would be impossible to know; right?

MR. HORNE: Argumentative, lacks foundation.

A. I would assume an order of an instrument would have documentation behind it.

BY MR. HANKINSON:

Q. So when you make a statement in your rebuttal declaration and you say that it's from your personal knowledge, it may or may not also be based on a document that you don't cite if it's a document that you think we ought to know exists?

A. I'm sorry, I'm not clearly understanding the question you're asking me.

Q. Well, there's a reason we cite sources of knowledge; right?

A. Yes.

Q. So that when the reader reads an assertion, if they want to check the source they can do so; right?

A. Yes.

Q. And so in this case had there been a citation here to a document and had Illumina provided that document to Meridian, then the reader could have checked

that document for him or herself and seen whether you had misinterpreted the record; right?

A. Yes, that true.

Q. But because there is no citation and no document that has been provided, the reader would not be able to check that?

A. That's true.

Q. But this statement makes no differentiation between your personal knowledge and knowledge that comes from a document that you're interpreting?

A. No, it doesn't.

Q. So then my more general question was if you will make a statement here that relies on your interpretation of Illumina's records but not cite it, how is someone reading this declaration supposed to know what is coming from your personal knowledge and what is coming from your interpretation of Illumina's records?

A. I don't know.

Q. So when you said in paragraph 1 "I have personal knowledge of the matters set forth herein and if called upon to testify I could and would competently testify thereto," are you including in your

understanding of personal knowledge your interpretations of Illumina's documents?

A. The -- my knowledge of that evaluation and potential sale was not exclusively based on the customer record. I thought I confirmed what I believed to be true by looking at it, but I was wrong.

MR. HANKINSON: Could you repeat my question, please.

(Question was read.)

A. Yes.

BY MR. HANKINSON:

Q. At what point in the year in 2007 did you join Illumina?

A. I want to say it was October. It was right after the big fires in San Diego in 2007.

Q. Were you there when Illumina acquired the company that made BeadXpress?

A. No.

Q. So you weren't personally involved in conversations about Illumina's intent when it acquired the company that made BeadXpress?

A. I was a part of conversations about why we

bought that company. It was clear to me when I took that job -- when I took my job what it was, was to realize the opportunity of the BeadXpress acquisition.

Q. So people told you when you came on board what Illumina had intended when previously it had acquired BeadXpress?

A. Yes.

Q. And that's the basis on which you talk about that matter?

A. Yes.

Q. When did Illumina collaborate with the University of Maryland School of Medicine?

A. What paragraph are you on?

Q. Do you remember without looking?

A. It was in the early years that I was at Illumina. I don't remember the exact date.

Q. Did you check the date with documents before you made your rebuttal declaration?

A. Yes.

Q. Okay. So look at paragraph 18. It says, "In 2007 Illumina collaborated with the University of Maryland School of Medicine in connection with a grant

received by the Gates Foundation to use the VeraCode and BeadXpress platform to detect the microbial pathogens that contribute to diarrheal disease, (i.e infectious diseases, including's C difficile)."

Right?

A. Yes.

Q. Is there a document cited in paragraph 18?

A. No.

Q. Did you work on this collaboration?

A. I was managing the -- I was responsible for the bead plates that were used in the GoldenGate genotyping technology that was used. So I was peripherally involved with it.

Q. Did you join Illumina in a marketing function?

A. Yes.

Q. Were you involved in any scientific or research roles in the collaboration with the University of Maryland?

A. No.

Q. Were you involved in overseeing that project?

A. No.

Q. Did Illumina or University of Maryland

personnel who were working on that collaboration report to you about their methods and their results?

A. Define "report."

Q. Tell you.

A. Yes.

Q. In 2007?

A. Around that time frame.

Q. Through a publication or something that was actually a communication to you personally?

A. A communication.

Q. Was it by email?

A. No.

Q. Was it by letter?

A. No.

Q. Meeting?

A. Yes.

Q. Did you meet with the University of Maryland personnel?

A. No.

Q. So you met with the Illumina personnel?

A. Yes.

Q. And they told you about the collaboration?

A. Yes.

Q. Was anyone treated by the people from Illumina or the University of Maryland who worked on that collaboration?

A. What do you mean "treated"?

Q. Was anyone who had an infectious disease treated?

A. By Illumina people?

Q. Or by University of Maryland people.

A. I don't know.

Q. You don't know one way or the other?

A. No.

Q. You would have to look at a document to know?

A. Yes.

Q. In paragraph 18 you're using this example to argue that Illumina had a presence in the infectious disease market; right?

A. Yes.

Q. And so when you refer to the infectious disease market in your rebuttal declaration, you don't necessarily mean the market to treat infectious disease, but rather something else?

MR. HORNE: Vague.

A. This particular example was a development program with the intention of making a product to treat. I don't know whether or not it was used for that purpose.

BY MR. HANKINSON:

Q. So you do know that it was only a development program; right?

A. I do know that it was at least a development program. I do not know if it was used to treat a patient or not.

Q. You do know that in 2007 it was a development program; right?

A. Yes.

Q. And you don't know whether any product came out of it that actually treated anyone?

A. I do not know that.

Q. But you are using it as your example in paragraph 18 for presence in the infectious disease market?

A. Yes.

Q. If a product came out of it, it wouldn't have

been in 2007, would it have been?

A. No.

Q. Do you understand that Meridian's application to register the brand Illumigene was filed in 2008?

A. Yes.

Q. In paragraph 17 you say, "Since at least 2007 Illumina's products could be utilized specifically for work with infectious diseases. In particular, BeadXpress could be used to identify diseases, whether genetic and inherited, or infectious diseases based on the DNA makeup of the disease"; right?

A. Yes.

Q. In 2007 did you witness a use of the BeadXpress product for clinical diagnostic purposes personally?

A. Did I see someone doing that?

Q. Correct.

A. No.

Q. Your statement in paragraph 17 is, rather, that it could have been done in 2007; is that accurate?

A. Yes.

Q. Meaning as a technological issue it was possible to do so?

A. That's what I'm saying there, yes.

Q. And if the board that decides this case takes the view that what matters is how products were being marketed and sold as of the relevant dates and not what they were technically capable of doing, then this example in paragraph 17 would not be relevant; correct?

MR. HORNE: Argumentative, lacks foundation, calls for a legal conclusion.

A. I don't know if it's relevant to them or not.

BY MR. HANKINSON:

Q. In any event, it's not an example of how a product was actually marketed to be sold in 2007?

A. That paragraph 17 does not provide an example of how it was marketed.

Q. This section of your rebuttal report, paragraph 16 through paragraph 30, are titled "Illumina Has a Presence in the Infectious Disease Market"; right?

A. Yes.

Q. So paragraph 17 is meant to support that premise?

A. Yes.

Q. But it is not a statement of how the BeadXpress

was marketed in 2007; right?

A. That statement is talking about the technical capability, not how it was marketed.

Q. Paragraph 17 and 18 are the only paragraphs in this section called "Illumina Has a Presence in the Infectious Disease Market," which spans paragraph 16 through 30, that come prior to 2009; right?

A. Yes.

Q. In paragraph 19 you say, "In 2009 Illumina explored the use of its BeadXpress platform with EraGen," E-R-A capital G-E-N, "to identify various flu-causing viruses/bacteria by the DNA makeup of the same"; right?

A. Yes.

Q. And was that a collaboration with EraGen to explore that use of the BeadXpress platform?

A. Yes.

Q. It was not a marketed product of the BeadXpress platform for identification of causing viruses or bacteria to anyone besides the collaborators, Illumina and EraGen; right?

A. I did speak probably about the relationship

with EraGen.

Q. Could you answer my question; and then if you want to add something, you can.

Could you read it back, please. Thank you.

(Question was read.)

A. It was not a marketed product.

BY MR. HANKINSON:

Q. In paragraph 20 you say, "To encourage development of diagnostics related to complex diseases, including infectious diseases, in 2010 Illumina created the VeraCode Assay Design Challenge. Illumina granted an award to the Royal Women's Hospital in Melbourne for the development of diagnosis methods for infectious urethritis." Right?

A. Yes.

Q. The Royal Women's Hospital in Melbourne, is that Australia or Canada?

A. Australia.

Q. And, in any event, this contest occurred in 2010; right?

A. Yes.

Q. And it was specifically to encourage the

development of diagnostics; right?

A. Yes.

Q. So the development of future products, not the marketing of existing products in the diagnostics field; right?

A. Yes.

Q. Then in paragraph 21 you state, "In addition, in 2010 Illumina had development programs for tests related to detecting multi-drug resistant organisms"; right?

A. Yes.

Q. And you say, "Both of these development programs were presented at an Illumina marketing external seminar series"; right?

A. Yes.

Q. So would you agree that there is a difference between presenting a development program and presenting a product?

A. Yes.

Q. And in 2010 these development programs that you're referring to in paragraph 21 did not have marketed products associated with them, rather they were

intended to develop such products in the future; right?

A. Yes.

Q. And that program is what was presented at the seminar series you're talking about; right?

A. No.

Q. You say both of these development programs were presented at Illumina marketing external seminar series; right; so is that an inaccurate statement?

A. The clarification would be we are presenting the product idea and stating we're developing something.

Q. That's not what the sentence says. It doesn't say "product idea"; right?

A. The --

Q. Could you first please tell me if the sentence includes the words "product idea"?

A. No.

Q. It does not; right?

A. No.

Q. Please go on, then.

A. I believe the exhibits provide an example of what we shared with customers in regards to what we said about these development programs.

Q. And there was a prospective idea of a product that was presented?

A. Yeah.

Q. Not a marketable product as of 2010?

A. Not a purchasable product.

Q. Do you think it's that a product to be used in the infectious disease market ought to be marketed before it exists?

A. It can be, yes.

Q. To develop the hype?

A. Awareness.

Q. You don't like the word "hype"?

A. No.

Q. Develop awareness?

A. Awareness.

Q. Awareness that something was coming in the future, though; right?

A. Yes.

Q. Did you know if -- Well, first of all let me say paragraph 21 does not say whether any product that was presented as an idea at the seminar series actually became a product for sale. That's not in paragraph 21,

is it?

A. It's not.

Q. And that didn't happen in 2010; right?

A. It did not.

Q. And your declaration does not say whether it happened at any future point?

A. It does not.

Q. In paragraph 22 you say that "In January 2011 Illumina acquired Epicentre Biotechnologies Corporation."

And they had a kit that provided a simple method for extracting DNA for use with a variety of applications, such as creation of lab-developed tests; right?

A. Yes.

Q. And you say that that kit has been tested with a range of bacteria; right?

A. Yes.

Q. This is the -- now, was this -- this Epicentre product was a product available for sale in 2011; right?

A. Yes.

Q. That's the first product in the section of your

declaration on infectious disease where the date of the paragraph is the date on which the product was available for sale in the way it's described in your rebuttal declaration; right?

A. The components described in paragraph 17 that were possible to be used for infectious disease and inherited disease and genetic disease in paragraph 17 were available in 2007.

Q. But all of the statements that you made to me today about paragraph 17 still hold true; right? You're not trying to withdraw any of those?

A. You asked me if this paragraph said that -- this paragraph explicitly talked about marketing, and it did not, but those products were marketed. They were available.

Q. Could you answer my question.

A. I'm not withdrawing anything I said previously.

Q. In paragraph 22 the Epicentre kit, that was -- was that an RUO-labeled product?

A. I don't know what the label of that product is.

Q. You only assert it could be used in lab-developed tests. You don't say that it could be

used to treat an infectious disease as an IVD product in this paragraph; right?

A. No, I don't.

Q. And do you believe that to be the case?

A. Yes. That's true.

Q. And then in paragraph 17 the BeadXpress was cleared by the FDA for a clinical diagnostic use in September 2009; right?

A. Yes.

Q. And that's the date on which you and Illumina's CEO, Mr. Flatley, disagreed about whether that was entering the diagnostics market, as he put it, or, as, you put it, continuing in the diagnostics market?

MR. HORNE: Lacks foundation, argumentative, mischaracterizes testimony.

A. I don't believe that I disagreed with Jay. I said something different than he did, but it's not -- I didn't disagree with him.

BY MR. HANKINSON:

Q. But you said something different than he did?

A. Yes.

Q. And somebody who was reading both statements

could decide whether they are different in a meaningful sense or a disagreement, as I might put it, or whether there is some harmonious resolution of the two?

A. Yes.

Q. In paragraph 23 it says, "In 2011 Illumina collaborated with Siemens Healthcare to develop an assay to detect HIV."

Do you see that?

A. Yes.

Q. Was a product to detect HIV marketed by Illumina in 2011?

A. No.

Q. So this is another development program; right?

A. Yes.

Q. And this paragraph does not say when or if such a product ultimately was sold?

A. No.

Q. What is the relationship, if anything, between a biosafety level 2 lab and a CLIA certified lab, or are they two separate things?

A. Not necessarily. Biosafety level 2 is talking about a level of risk involved in touching hazardous

materials, biological substances that could cause the user harm.

In a CLIA -- shall I continue? CLIA high complexity is about the level of complexity of an assay procedure. How those two are related is not something I fully understand.

Q. In the last sentence of paragraph 23 you say that companies build these biosafety level 2 labs to be able to work with infectious diseases; right?

A. Yes.

Q. Those companies there include hospital laboratories?

A. Yes.

Q. And that's a prerequisite, then, for working with infectious disease?

A. Depending on the type of disease, the risk involved and the way that they are being handled, it can be required.

Q. Have you taken any effort to determine the percentage of hospital labs that deal with infectious diseases that are also biosafety level 2 labs, compared to the total of such labs?

A. No.

Q. So you don't have a sense of -- let me start again.

Do you have an estimate of that percentage?

A. No.

Q. It could be anything from 1 percent to 99 percent?

A. I don't want to speculate on a percentage. I don't know.

Q. You say that a biosafety level 2 lab requires that laboratory personnel receive specific training in handling pathogenic agents; right?

A. Yes.

Q. And also that it be directed by scientists with advanced training; is that right?

A. Yes.

Q. What kind of advanced training do the scientists who run a biosafety level 2 lab have to have?

A. An understanding of the risk involved with interacting with infectious agents like HIV.

Q. So it's awareness training?

A. Yes. Preventative measures from harming

themselves or others interacting with products or waste.

Q. Do the -- You say "directed by scientists with advanced training."

Is there some requirement that there be scientists running these labs, or maybe I should just ask generally why did you use the word "scientists" there?

A. The individuals interacting with these consumables would have some scientific or biomedical training.

Q. Is that also true of the personnel who would be key stakeholders in purchasing decisions for equipment and consumables at the lab?

A. Are the individuals the same?

Q. No. Would it be true that those people would also have some sort of scientific education?

A. It depends on the situation.

Q. So in labs that deal with infectious disease, the stakeholders in purchasing decisions as to equipment and consumables vary across the market in terms of their education?

A. That's not what I'm saying.

Q. So there is some level of education that is consistent across that market for people making the purchasing decisions?

A. I -- can you please restate your question.

Q. Sure. First I asked in the infectious disease market is there some level of -- excuse me.

First I asked in the infectious disease market does it vary across the market what level of education the stakeholders in purchasing decisions have, and you said you're not saying that.

So then I asked so is there some --

A. Can I just think about what you just said to me for a second?

Q. Sure.

A. Okay. I'm sorry. Continue, please.

Q. And you're okay with your answer on that, that wasn't what you were saying?

A. (No audible response)

Q. The new question is is there some consistent level of education in infectious disease -- excuse me.

Is there some consistent level of education that the stakeholders in purchasing decisions of labs

that deal with infectious disease have? Is there not some consistent level of education that they have? And you can say yes or no to that and then go on to, like, more specifics.

A. And qualify it?

Q. Yeah, sure.

A. So yes, a lab director usually has some scientific education. The reason I wasn't generalizing across all stakeholders is because a hospital administrator may be a business person, and they may not have scientific training. That why I answered in that way.

Q. And so the stakeholders include both lab directors and hospital administrators?

A. It can.

Q. Or it could be one or the other?

A. It could be.

Q. And on the lab director's side, they have a certain level of scientific education?

A. Usually, yes.

Q. Usually a lab director would have a Ph.D.?

A. Or an M.D.

Q. Or an M.D. And in a high complexity CLIA lab, the lab director would have an M.D.-Ph.D; right?

A. Not necessarily.

Q. But commonly?

A. Not necessarily.

Q. But commonly?

A. No.

Q. So it would be uncommon to have an M.D.-Ph.D. being a lab director of a CLIA high complexity lab?

MR. HORNE: Mischaracterizes testimony.

A. I can't speculate on the percentage that have an M.D.-Ph.D.

BY MR. HANKINSON:

Q. You just don't know?

A. I don't know.

Q. The lab directors of high complexity CLIA labs would typically have a higher level of education than the lab directors of labs that are not; right?

A. I don't know that to be true.

Q. It varies across the board?

A. No. No. My -- can I qualify my answer?

My understanding is that the lab director to

sign off a report, which is practicing medicine, is either an M.D. and in some situations maybe a Ph.D. with a license in genetics or some other specialty.

Q. And that applies to the stakeholders in the purchasing decisions in labs that deal with infectious diseases on the lab director's side?

A. Yes.

Q. And then on the hospital administrator's side of those stakeholders, they would typically have at least an undergraduate degree; right?

A. I would assume.

Q. And often a master of business or a business degree of some sort?

A. Maybe.

Q. On the hospital administration side, part of their job duties are specifically to purchase products and to enter into contracts for the purchase of products with suppliers of products; right?

A. One example of a stakeholder in hospital administration would perform that role.

Q. Being the purchasing department?

A. Yes.

Q. And the other example would be the C-Suite of the hospital --

A. Yes.

Q. -- who would typically have either more education or more experience than the folks staffing the purchasing department?

A. Yes.

Q. So on the administration side, the stakeholders are either someone whose job responsibilities include specifically the purchase of products and the negotiation of contracts for the purchase of products, or it would be somebody with a little bit more education and responsibility than that person?

A. Yes.

Q. In paragraph 24 you say, "In November 2011 Illumina collaborated with Siemens Healthcare Diagnostics to make Siemens' molecular HIV tests compatible with Illumina's MiSeq" -- all these SEQs are S-E-Q -- "platform and to develop additional sequencing-based infectious disease assays.

"For the clinical diagnostics market through its venture with Siemens, Illumina saw additional

adoption of its next-generation sequencing (NGS) technology, in the clinical diagnostics market."

Is that that paragraph?

A. Yes.

Q. So Siemens had an HIV test; right?

A. Yes.

Q. And Illumina had a MiSeq platform? Yeah?

A. Yes.

Q. In 2011?

A. Yes.

Q. But it was late 2011 when -- November 2011 when the two companies began collaborating to put that HIV test onto Illumina's MiSeq platform?

A. Yes.

Q. This paragraph does not identify whether a product for sale came out of the collaboration; right?

A. It does not.

Q. And, in any event, there was no such product in 2011?

A. No.

Q. And then that next sentence, "Through its venture with Siemens, Illumina saw additional adoption

of the NGS technology."

It's not saying that there were sales related to the venture with Siemens; right?

A. Sales related to the venture of Siemens would be included in that statement.

Q. When was MiSeq cleared by the FDA for IVD?

A. 2010.

Q. And that was that factor 5, factor 2?

A. It was cystic fibrosis, any universal kit.

Q. I thought it was 2013. Am I just getting fuzzy?

A. I might be wrong. I'm sorry. It's late. I might have the dates wrong for MiSeq DX approval. I apologize.

Q. Do you remember now, or are you having trouble?

A. I'm having a hard time placing the date.

Q. In paragraph 25 you say, "Further, to promotional and marketing activities mentioned in my previous declaration, both Illumina and Meridian also attend the American Society for Microbiology events.

In 2013 and 2014 both Illumina and Meridian have been exhibitors at the American Society for

Microbiology annual meeting"; right?

A. Uh-huh, yes.

Q. It's a trade show?

A. Yes.

Q. Is paragraph 26 talking about that Gates Foundation thing or something else?

A. It's talking about something else.

Q. So what's the date for what's happening in paragraph 26?

A. It's related to the microbiology group that was formed in 2010 in the paragraph below to respond to adoption of the technology for the use described in -- I'm sorry, in paragraph 26.

Q. Epidemiology?

A. Yes.

Q. Tracing a possible, you know, outbreak to see whether the strain is the same as elsewhere or different to determine whether it's the same strain that's spreading from some sort of common source. That's what paragraph 26 is about?

A. Yes.

Q. A patient, an individual patient doesn't

require knowledge of which strain of the infectious disease is infecting them in order to be treated, do they?

A. I think that they do need that.

Q. Sometimes but not all the time?

A. I don't know how frequently they need it to happen, but I know of examples when they need to know.

Q. Those would be examples where you would use a technology that identifies the strain; right?

A. Yes.

Q. And, in contrast, if you're dealing with an infectious disease where you can treat it without knowing the strain, then you can use a technology that would just tell you yes or no, does the patient have this infectious disease?

A. I'm sorry, can you restate what you're saying?

Q. Sure. When you don't need to know the strain in order to treat the patient, you can use a technology that just tells you yes or no, does the patient have this infectious disease?

A. Yes.

Q. Is the microbiology group an internal group of

Illumina?

A. Yes.

Q. And the collaboration with BioMerieux in paragraph 28 happened in 2014; right?

A. Yes.

Q. Just last year?

A. Yes.

Q. And paragraph 28 says that the companies plan to jointly develop a pathogen genome database; right?

A. Yes.

Q. And in paragraph 28 it says, "This product will be a sequencing solution dedicated solely to the detection of infectious diseases"; right?

A. Yes.

Q. So this is not a product that exists right now in a salable state?

A. No, not to my knowledge.

Q. In paragraph 30 you say, "When an outbreak is suspected, hospitals will commonly collect samples from patients and the environment and send them to a clinical microbiology lab for testing. Clinical microbiology labs will then use Illumina's sequencing products to

analyze the samples, compare them to others, and inform the hospitals of whether or not there has been an infectious disease outbreak"; right?

A. Yes.

Q. That's something that the Illumigene and Illumipro products from Meridian cannot do; right?

A. I don't know whether they can do that or not.

Q. You have no idea one way or the other?

A. I don't know.

MR. HORNE: Is this a good time for a break?

MR. HANKINSON: Yes.

(Recess was taken from 4:06 until 4:24 p.m.)

MR. HANKINSON: I'd like to mark this document as Exhibit W.

(O'Grady Exhibit W was marked for identification)

MR. HANKINSON: Mr. Noon, I'm sorry I didn't bring a copy this time.

MR. NOON: That's all right.

BY MR. HANKINSON:

Q. Ms. O'Grady, this is a declaration of an employee of Meridian named Michael Patrick, and the date

on this declaration is June 29th, 2012. Okay?

A. Okay. Did you have a copy for me?

Q. Yeah, right here. It's marked with a big W.

And so 2012 predates any declaration by you in this matter; right?

A. Yes.

Q. Okay. And it also predates any declaration by a Mr. Heath from Illumina; right?

A. I don't know when he did a declaration.

Q. But this has to do with summary judgment, whereas Illumina submitted declarations after the summary judgment period for testimony purposes. Do you understand what I'm saying?

Brian, do you have any objection to my representations?

MR. HORNE: No.

BY MR. HANKINSON:

Q. So could you turn to paragraph 8. And actually looking at the heading above that, it says "The Differing Consumers of Meridian's Products versus Illumina's From 2008 to Today."

Do you see that heading?

A. Yes.

Q. In paragraph 8, the second paragraph under that, it says "Within the broader category of infectious disease, Meridian's clinical diagnostic products are focussed in the microbiology space. Meridian's 'molecular diagnostic' products test for and identify the microbial invader; Meridian's products do not focus or have any relationship to the genetics of the human patient."

Do you see that?

A. Yes.

Q. Mr. Patrick is trying to make the distinction between the genetics of the microbial invader and the genetics of the human patient; right?

A. Yes.

Q. And the products that are addressing those needs; right? He's trying to make a distinction between those products?

A. Yes.

Q. And the markets for those products, the differing consumers of Meridian's products versus Illumina's?

A. He doesn't say anything here about consumers.

Q. Let's go to paragraph 14.

A. Okay.

Q. "Illumina is not and has not been a competitor of Meridian and does not offer goods to the same consumers as Meridian. Because of the line of business Illumina is in, Illumina's consumers, where they otherwise overlap in the larger hospital lab and reference lab channel of trade, are those on the research side of such labs. Outside of this channel, Illumina also markets to and serves dedicated research institutions where human genomes are sequenced on a massive scale for, among other things, drug development purposes. Meridian has no involvement in this space whatsoever."

Are you with me there?

A. Yes, I see that.

Q. And then in paragraph 16 Mr. Patrick said, "In 2008 Illumina did not offer any clinical diagnostic products whatsoever and did not offer any products or services related to infectious diseases or microbiology. Rather, Illumina was a company that offered human

genetic sequencing services and supplied equipment and components for companies and laboratories to construct their own assays (scientific tests). Those products and services are directed toward and used by an entirely different category of consumers from consumers of clinical diagnostic products."

Are you with me there?

A. Yes. I see what that says.

Q. So Mr. Patrick is trying to make the distinction that in your rebuttal declaration you are trying to disagree with that there is a distinction between Meridian's products being directed to the area of infectious disease and, on the other hand, Illumina's products being directed to people asking questions about human genetics.

Do you disagree with that --

A. Yes.

Q. -- in your rebuttal declaration?

A. Yes.

MR. HORNE: Done with this?

MR. HANKINSON: Probably. You never know. I want to mark this as Exhibit X.

(O'Grady Exhibit X was marked for identification)

BY MR. HANKINSON:

Q. This Exhibit X is a declaration of Gregory F. Heath, who's an employee of Illumina; right?

A. He was at the time.

Q. He is no longer with the company?

A. No.

Q. And if you look at page 12, he signed this declaration on November 7th, 2014; right?

A. Yes.

Q. Mr. Patrick's declaration is from 2012; Mr. Heath's is from 2014. Right?

A. Yes.

Q. Could you find Exhibit 121 wherever Mr. Heath refers to it.

It's taking some time. Would you agree there is a great deal of information in Mr. Heath's declaration?

A. I found it.

Q. Very good. What paragraph?

A. 30.

Q. Would you agree that there is a lot of material prior to that?

A. There is 29 paragraphs before that.

Q. Very nice, of varying length.

A. Of varying length.

Q. Paragraph 30 refers to Exhibit 121; right?

A. Yes.

Q. And it says "true and correct copies of advertisements and trade show exhibitor lists are attached hereto as Exhibit 121"; right?

A. Yes.

Q. It does not say anything about infectious diseases here, does it?

A. It does not qualify the market segment in any way.

MR. HANKINSON: I only brought one copy of this Exhibit 121, and I'd like to mark it as Exhibit Y.

(O'Grady Exhibit Y was marked for identification)

MR. HANKINSON: I don't have a copy of this either. I'm sorry. I'll have to impose on you to share.

Q. So here is Exhibit 121. Using this exhibit, would you please tell me what I should be gleaning about market segments and specifically infectious diseases, if anything, from Mr. Heath's statement and from Exhibit 121.

MR. HORNE: Vague. I also object to the extent it calls for a legal conclusion.

BY MR. HANKINSON:

Q. Let me interrupt you as you leaf through Exhibit 121 --

A. Okay.

Q. -- and ask you if Illumina or Mr. Heath had intended for Meridian to be able to glean something from paragraph 30 and Exhibit 121, would it have been helpful to provide page numbers and an explanation of what about the market segments ought to be gathered from the statement in the exhibit?

MR. HORNE: Lacks foundation, argumentative, calls for a legal conclusion.

A. Are you asking me if it would be helpful?

BY MR. HANKINSON:

Q. To have a page number to look at for whatever

is supposed to discuss infectious diseases or market segments.

A. Yes, that would be helpful.

Q. And have you figured out if it says anything about market segments, in particular infectious diseases yet?

A. I'm trying to understand what trade shows are included in this stack.

Q. It doesn't say in paragraph 30, does it?

A. No, it doesn't.

Q. Actually paragraph 30 refers to exhibitors at trade shows, right, exhibitor lists --

A. Yes.

Q. -- as opposed to attendee lists?

A. The paragraph says that we're exhibiting to the same set of consumers at the same trade shows, which would imply the attendees are overlapping.

Q. But the exhibitor lists would be expected to show whether Illumina and Meridian were both exhibitors, right, as you read paragraph 30?

MR. HORNE: Argumentative, lacks foundation.

A. It does imply that, and it does show that.

BY MR. HANKINSON:

Q. Do you think it's a reasonable --

A. At least AACC, the first one I looked at.

Q. Do you think that's a reasonable interpretation of what paragraph 30 in Exhibit 121 should mean to a reader?

MR. HORNE: Lacks foundation, argumentative.

BY MR. HANKINSON:

Q. I mean it's your interpretation, and you're a reasonable person; right?

A. Yes and yes.

MR. HANKINSON: I'd like to mark Exhibit Z.

(O'Grady Exhibit Z was marked for identification)

MR. HANKINSON: This is a document provided by Illumina labeled as page ILLUM-1558, and I will note that this does say Trade Secret/Commercially Sensitive on it. I don't think we're going to discuss any commercially sensitive information in the transcript, but be aware.

MR. HORNE: Okay.

////////

BY MR. HANKINSON:

Q. Look at the second page of Exhibit Z, if you would, please.

A. Okay.

Q. There is a column on the left called Institution; right?

A. Yes.

Q. There is a column on the right called Title of Person, quote, "responsible for order," unquote; right?

A. Yes.

Q. Okay. Do you recognize the institutions listed in the column on the left? There is 25 of them.

A. Yes.

Q. They are large customers of Illumina; right?

A. Yes.

Q. Illumina identified these as their 25 largest customers in discovery at a certain point in time in this case. Okay?

A. Okay.

Q. And then Illumina identified the people or -- excuse me -- the positions on the right column as the title of the person responsible for the order. Okay?

A. Yes.

Q. Review this. Review the titles of the people responsible for the order and count how many are not sort of professional supply chain or purchasing personnel. In fact, why don't you call out the line numbers when you find some.

A. Line 5 is a Researcher. Line 16 is a Researcher. Line 21 is Program Coordinator, which is a little ambiguous as to what that is. 25, Life Science Research Assistant.

Q. So out of these 25 largest customers of Illumina, the person responsible for the order in 21 of them has a professional role related to purchasing or supply chain management; right?

A. Yes. That's implied.

Q. And 3 out of the 25 have some sort of either researcher or life science research assistant; right?

A. Yes.

Q. And then one of the 25 has a title Program Coordinator; right?

A. Yes.

Q. Do you have any knowledge -- let me start

again.

Do you think that Illumina's top 25 customers are atypical in some sense in terms of who is responsible for the order, or do you think this is a pretty typical ratio of the titles of the people that are responsible for ordering from Illumina?

A. It -- I don't have an opinion.

Q. No opinion one way or the other?

A. No.

Q. Were you surprised in any way to see this ratio?

A. I had no expectations.

Q. And this list of titles agrees with our discussion from earlier today about stakeholders in the purchasing decision. Some of these -- most of these are on the hospital administration side or the lab administrative side, and then some of them are on that research side?

A. As a stakeholder responsible for an order, yes.

MR. HANKINSON: All right. Let's mark Exhibit -- let's make this L. Can we make it Exhibit L?

MR. HORNE: You don't want to make it double A?

MR. HANKINSON: I want to make it Exhibit L.

(O'Grady Exhibit L was marked for identification)

BY MR. HANKINSON:

Q. This is a declaration from a guy named Paul A. Granato.

Do you see that?

A. Yes.

Q. And Mr. Granato does not work at Illumina or Meridian. He's currently the director of microbiology -- excuse me -- as of this declaration, he says he is currently the Director of Microbiology at the Laboratory Alliance of Central New York, located in Liverpool, New York; is that right?

A. Yes. I'm sorry, wait a second. This is Syracuse, New York.

Q. Oh.

A. Hold on a second. I'm sorry. Yes, it says Liverpool, New York.

Q. Okay. And then on the last page it's dated, it says, June 29th, 2012; right?

A. Yes.

Q. Okay. Do you have any -- do you know Mr. -- Dr. Granato?

A. I don't think so, no.

Q. Do you have any awareness of the Laboratory Alliance of Central New York?

A. I'm not directly involved with them, no.

Q. So no awareness?

A. No.

Q. In this declaration he states that as Director of Microbiology he is responsible for the operational activities and diagnostic testing for this full service laboratory that provides diagnostic testing in the areas of bacteriology, virology, mycology, parasitology -- I'm sorry -- bacteriology, virology, mycology, parasitology, and mycobacteriology.

Do you see that sentence?

A. Yes.

Q. If that's true, would you believe that Dr. Granato's lab is in the relevant market for Illumina's branded products and Meridian's branded products that are at issue in this dispute?

MR. HORNE: Vague, calls for a legal

conclusion.

A. It could be.

BY MR. HANKINSON:

Q. It may or may not be? Is that what you're saying? You don't have enough information to tell if Mr. Granato's lab is in the market?

A. I would -- Based on the information provided, it looks like he would be a prospective customer of either Illumina or Meridian.

Q. Could you turn to page 3 -- excuse me, I'm sorry -- page 2, paragraph 8. It's titled -- there's a heading, Purchasing Products in a Clinical Diagnostics Laboratory. Do you see that?

A. Yes.

Q. Then paragraph 8 says, "The typical situation which I describe below is true of my current laboratory and the other laboratories in which I've worked."

All right. And then he goes on to describe this situation. You with me?

A. Yes.

Q. Okay. I want to go through this with you and ask you about paragraph 9. "There are typically several

specializations within a clinical diagnostics laboratory, including, for example, microbiology, chemistry, hematology, special chemistry and/or others. Each department has a manager or supervisor."

Do you agree or disagree with the statements in paragraph 9?

A. I disagree.

Q. Okay. What is the -- What do you disagree about?

A. The generalization that every department has a manager or a supervisor.

Q. That could vary across the board?

A. It could vary across the board.

Q. So somebody trying to prove that particular brand names are likely to be confusing to consumers in a market would need to demonstrate whether the relevant consumers are headed by a manager or supervisor, wouldn't they, or else you just wouldn't know?

MR. HORNE: Calls for a legal conclusion.

A. I don't have an opinion as to whether determining if the managers or supervisors are the same is important.

BY MR. HANKINSON:

Q. So whether a department -- You don't dispute these departments exist in a clinical diagnostics laboratory?

A. They can.

Q. They can. And do you agree that typically there is at least several specializations within a clinical diagnostics laboratory?

A. There can be.

Q. And so your issue is with whether they are headed by a manager or a supervisor?

A. You know, actually the statement doesn't say it's a distinct manager or supervisor. So one would assume that these departments are managed by someone. I inferred that it was distinct. It doesn't say that.

Q. And then in paragraph 10 he states, "The manager/supervisor of each department may have products that he or she identifies as needed for the department's work. The manager/supervisor gives the product description, or often a catalogue number and supplier name, to the purchasing agent or laboratory's purchasing department.

"The purchasing agent or the purchasing department will locate a supplier for the product and place an order under a prenegotiated contract with a supplier that includes set pricing. Sometimes, for products that are known to be needed in a certain quantity on a regular basis, standing orders will be set up without the need for separate purchase orders that would otherwise be required each week or each month. Again, such products are covered by a prenegotiated contract that includes pricing."

Do you agree or disagree with paragraph 10?

A. This description seems to be reasonable for a lab that has a purchasing department supporting them and provides a general description of the protocol under Granato's experience.

Q. Then in paragraph 11 he states, "Purchasing departments or purchasing agents are typically responsible for selecting manufacturers and distributors and negotiating contracts with them under which individual orders for products are placed. The manager/supervisors of the laboratory departments request the products that are needed, but the purchasing

personnel of the laboratory typically choose the vendor to supply the products and set up the contracts if more than one vendor provides the same product."

Do you agree or disagree with paragraph 11?

A. I disagree with paragraph 11.

Q. Let's take the first sentence. Do you disagree with anything in that?

A. I disagree with the part that says "responsible for selecting manufacturers."

Q. Who do you think are typically responsible for selecting manufacturers?

A. The lab director is directly involved with that --

Q. Meaning --

A. -- or other stakeholders.

Q. -- both have involvement; there is a group of people, not just the purchasing department?

A. Yes. That's right.

Q. But you don't disagree -- excuse me. You agree that purchasing departments are typically involved?

A. If there is one available for an institution, yes, I would assume they would be involved.

Q. And do you have knowledge of the percentage of institutions in the relevant market for this dispute that have purchasing departments available versus those that don't?

A. No.

Q. Do you disagree with anything in the second sentence of paragraph 11?

A. I disagree with the part that says "The laboratory typically chooses the vendor to supply the products if more than one vendor provides the same product."

Q. Again, are you -- is your disagreement based on there being more people responsible as stakeholders in that decision than just the purchasing personnel?

A. Yes.

Q. Do you have an opinion on whether the lab director is more likely to be directly involved in the purchase of equipment when the equipment is intended to be used in a laboratory-developed test versus when it's not?

A. No. I think it would be equally involved.

Q. Do you have an opinion on whether a lab

director at a CLIA high complexity lab is more or less involved in purchasing decisions than a lab director in a CLIA medium complexity lab?

A. No, I don't have an opinion about that.

Q. You don't know about the market in CLIA medium complexity labs?

A. I don't know about the relative involvement of a lab director in making the decisions in that space.

Q. In paragraph 12 Dr. Granato says, "When there is more than one vendor of the type of product that a purchasing agent needs to procure, he or she will usually solicit bids from the multiple vendors and select the best overall option. The selection is largely based on price, but other factors in the decision may include responsibility and reliability of the vendor from reputation or past experience."

Do you agree or disagree with paragraph 12?

A. I disagree.

Q. And what do you disagree with?

A. The paragraph 12 is assuming the product performance and features are equitable and the only basis of differentiation is price and support or

reputation.

Q. So product features would be -- and workflow would be factors that the stakeholders would also consider; right?

A. Yes.

Q. Before making a purchasing decision; right?

A. Yes.

Q. And to understand the features of the product and the workflow of the lab that would be required to implement the product, the stakeholders at a lab would need to get information from the source of the product about those features and that workflow; right?

A. Yes.

Q. And they'll procure that information before they make a final purchasing decision; right?

A. Yes. I would assume that to be true.

Q. And you believe it to be true as well --

A. Yes.

Q. -- based on your experience?

A. Yes.

Q. Look at the heading "The Sophistication and Attention Level of Purchasers in a Clinical Laboratory."

In paragraph 14 Dr. Granato says, "Everyone in a clinical diagnostics laboratory who is responsible for requesting or purchasing products is well-educated and highly sophisticated."

Do you agree or disagree with that?

A. Highly sophisticated, I don't know what is implied by that; but well-educated I would agree with.

Q. Paragraph 15 says, "The laboratory managers/supervisors typically have specialized post-grad scientific education and are experienced with requesting products for the laboratory and familiar with the products that are available and their sources."

Do you agree or disagree with paragraph 15?

A. I agree with everything up and to the end where it says "familiar with the products that are available and their sources."

Q. So you agree that the laboratory managers or supervisors typically have specialized post-grad scientific education?

A. Yes.

Q. And you agree that they are experienced with requesting products for the laboratory?

A. Yes.

Q. In paragraph 16 Dr. Granato states, "The very great majority of purchasing agents of clinical diagnostics laboratories have a college education and specialize in sourcing products, soliciting bids, negotiating pricing contracts, and purchasing products. They are typically experienced in purchasing for medical institutions and are intimately familiar with the manufacturers and suppliers in the market and the products that they supply."

Do you agree or disagree with the statements in paragraph 16?

A. I don't necessarily agree with intimate familiarity with manufacturers and suppliers in the market and the products that they supply.

Q. But you agree with the statements up until that phrase?

A. I also am not aware of what level of education these individuals may or may not have as a purchasing agent, whether or not they have a college education. But the experience and sourcing products and bids and negotiating and purchasing is something I understand and

agree with.

Q. In paragraph 17 Dr. Granato says, "In the field of microbiology within a clinical diagnostics laboratory the managers/supervisors and purchasing agents are usually very familiar with what diagnostic tests are available for various infectious diseases and what companies provide or offer those tests."

Taking just that sentence, do you agree or disagree with that?

A. I disagree.

Q. And what is the nature of your disagreement?

A. They may or may not be aware of new and emerging products as they come available. They would have to learn about those once they become available.

Q. So you agree that they are usually very familiar with what has been available in the past, but you're noting that when new products come out, of course they wouldn't already know about those?

A. Actually I am also uncomfortable generalizing that clinical diagnostic laboratory managers or supervisors and purchasing agents are very familiar with the products that are available.

It's very general, and I don't know who knows what or who may not know something. I don't -- I don't know that to be true as a generalization.

Q. You don't know one way or the other?

A. No.

Q. Do you agree that it is, as the second sentence says, their job to know the various diagnostic tests that are available for infectious diseases?

A. I would assume if they're buying new technology they need to investigate what's available and understand the options.

Q. And going on in that sentence, do you agree that although some of the product names are complex and although some of the product names are similar to one another, they are repeated with enough frequency that they are thoroughly learned?

A. I don't know if that's true.

Q. You just don't know?

A. I do not know.

Q. Let me ask you. If Dr. Young agrees with that statement on Friday, do you think he knows better than you do?

A. I don't know whether or not one could generalize, based on his experience, to the rest of the market.

Q. So he would only know his lab better than you? He wouldn't necessarily be able to generalize as to all labs?

A. Yes.

Q. And the same is true of you?

A. What are you asking me?

Q. You're not able to generalize as to all labs?

A. That's what I just said in response to this paragraph, that I don't know if all labs and purchasing agents are intimately familiar with what options are available and whether or not they would be confused.

Q. Do you think that you actually know whether, as a general matter, stakeholders in purchasing decisions in clinical diagnostic laboratories were aware of Illumina-branded products in the clinical diagnostics field prior to November of 2008?

A. I know of examples of that, of individuals we interacted with that were aware of us.

Q. And you've not provided a number as to how many

of those examples you know of in any declaration; correct?

A. I don't believe so.

Q. And you don't think that you can generalize to the rest of the clinical diagnostics laboratories based on those examples; you just don't know one way or the other?

A. I don't know what their purchasing agents do or do not know about what products are available. I don't know the answer to that.

Q. And now I'm asking you about stakeholders and purchasing decisions in clinical diagnostics laboratories prior to November 2008 and whether you can generalize from the examples that you know whether those stakeholders had awareness or not of Illumina-branded products in the clinical diagnostics field.

A. I'm sorry, that was a complex question. Can I hear it again?

Q. Sure.

Would you please read it.

(Question was read)

A. I'm sorry, you provided a date in 2008?

BY MR. HANKINSON:

Q. Prior to November 2008.

A. Yes. We had some level of awareness at that time with lab directors.

Q. And you're comfortable generalizing as to the entire market, not just speaking of the individual examples that you're aware of?

A. I don't think I am generalizing.

Q. Do you have a market study that shows awareness in that market segment as of prior to November 2008?

A. No.

Q. And you have not provided a number of examples or the total number of relevant entities within the market; right?

A. No.

Q. So you don't have a basis to calculate the percentage of awareness; right?

A. No.

Q. And so you would be generalizing, based on examples, if you were to make a conclusion about awareness in the general market; right?

A. Yes.

Q. So you're comfortable doing that, but you're not comfortable generalizing about the level of education, whether there are managers or supervisors or individual departments or the other things that you've disagreed with in Dr. Granato's declaration?

A. I am not comfortable speculating what I do not know in regard to those specific examples you just gave me.

Q. So when you generalize from examples without having a percentage, it's really speculation?

MR. HORNE: Argumentative.

A. That not what I said.

BY MR. HANKINSON:

Q. So you think there is a distinction with a difference between the two?

A. Yes.

Q. And it's that you just feel more confident about it?

A. I'm able to give a specific example in one case. I'm not in another. I don't know it to be true in any measurable way about what familiarity someone may have of products.

Q. So you have an example, and you're generalizing based on it when you're talking about the market for clinical diagnostic products prior to November 2008 with respect to awareness of Illumina-branded products in the market?

MR. HORNE: Argumentative, mischaracterizes testimony.

A. Yes.

MR. HORNE: You pretty close to stopping time?

MR. HANKINSON: Yeah, I'm pretty close. I'm not there.

Q. If I saw in an Illumina 10-K what the advertising spent was for the entire company in that year but it wasn't broken down between brands or market segments, does that provide me with information about how much money Illumina spent in that year to promote Illumina or IlluminaDX in the field of clinical diagnostics?

A. I have not looked at the Illumina 10-K to answer your question.

Q. Let's say it says that Illumina spent like $1.3 million in a given year on advertising, and that's all

it says. Okay?

A. Okay.

Q. Illumina has a lot of different advertising that it does; right? It advertises in a lot of different ways?

A. Yes.

Q. And to a lot of different market segments?

A. Yes.

Q. So I wouldn't know how much of that $1.2 million, as an example, would have been spent on the clinical diagnostic market segment; right?

A. That's correct.

Q. And I wouldn't know whether any of it had been spent advertising the brand IlluminaDX?

A. I don't believe that information is provided.

MR. HANKINSON: Okay.

MR. HORNE: Done? Let me contemplate. Let's go off the record.

(Brief interruption)

EXAMINATION

BY MR. HORNE:

Q. Okay. Mrs. O'Grady, earlier today you were

asked some questions about your understanding of what Illumina's recitation of goods meant.

A. Yes.

Q. There were some questions about the time period with which you were making your understanding?

A. Yes.

Q. Do you believe the recitation of goods would have any different meaning whether we're talking about 2015 or 2008 or any time before 2008?

A. No, I don't.

Q. Meaning you think the recitation would be the same for those time periods?

A. Yes.

MR. HORNE: Nothing further.

FURTHER EXAMINATION

BY MR. HANKINSON:

Q. In the year 2000 you were in undergraduate university; right? You said you graduated either then or 2001?

A. Yes.

MR. HANKINSON: Nothing further.

MR. HORNE: Nothing further in response to

that.

I'll just say you used some declarations from the summary judgment period. To the extent Meridian believes that using those declarations allows them to be admitted as testimony declarations, we would object to that.

MR. HANKINSON: We would just be relying on Ms. O'Grady's testimony.

MR. HORNE: We can sort that out later. Okay. No more questions.

(Whereupon at 5:25 p.m. the deposition was concluded)

- - -

REPORTER'S CERTIFICATE

I, KARLA MEYER BAEZ, Certified Shorthand Reporter No. 4506 for the State of California, do hereby certify:

That prior to being examined, the witness named in the foregoing deposition was duly sworn to testify the truth, the whole truth, and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named (including identifying the presence of all parties attending and the beginning and ending times) and thereafter reduced by me to typewritten form, and that the same is a true, correct, and complete transcript of said proceedings;

Before completion of the deposition, review of the transcript { } was {X} was not requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed, are appended hereto.

I further certify that I have no disqualifying interest, personal or financial, in any party.

Witness my hand this 20th day of May, 2015.

KARLA MEYER BAEZ, CSR NO. 4506

Naomi O'Grady c/o
KNOBBE MARTENS
10100 Santa Monica Boulevard
16th Floor
Los Angeles, California 90067

Case: Illumina, Inc. v. Meridian Bioscience, Inc.
Date of deposition: May 12, 2015
Deponent: Naomi O'Grady

Please be advised that the transcript in the above referenced matter is now complete and ready for signature. The deponent may come to this office to sign the transcript, a copy may be purchased for the witness to review and sign, or the deponent and/or counsel may waive the option of signing. Please advise us of the option selected. Please forward the errata sheet and the original signed signature page to counsel noticing the deposition, noting the applicable time period allowed for such by the governing Rules of Procedure. If you have any questions, please do not hesitate to call our office at (202)-232-0646.

Sincerely,
Digital Evidence Group

Digital Evidence Group, L.L.C.
1726 M Street, NW, Suite 1010
Washington, D.C. 20036
(202) 232-0646

SIGNATURE PAGE

Case: Illumina, Inc. v. Meridian Bioscience, Inc.
Witness Name: Naomi O'Grady
Deposition Date: May 12, 2015

I do hereby acknowledge that I have read and examined the foregoing pages of the transcript of my deposition and that:

(Check appropriate box):
( ) The same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.
( ) Except for the changes noted in the attached Errata Sheet, the same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.

_____ _____
DATE WITNESS SIGNATURE

_____ _____
DATE NOTARY

Digital Evidence Group, LLC
1726 M Street, NW, Suite 1010
Washington, D.C. 20036
(202)232-0646

ERRATA SHEET

Case: Illumina, Inc. v. Meridian Bioscience, Inc.

Witness Name: Naomi O'Grady

Deposition Date: May 12, 2015

Page No.	Line No.	Change

_____ _____

Signature Date

REPORTER'S CERTIFICATE

I, KARLA MEYER BAEZ, Certified Shorthand Reporter No. 4506 for the State of California, do hereby certify:

That prior to being examined, the witness named in the foregoing deposition was duly sworn to testify the truth, the whole truth, and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named (including identifying the presence of all parties attending and the beginning and ending times) and thereafter reduced by me to typewritten form, and that the same is a true, correct, and complete transcript of said proceedings;

Before completion of the deposition, review of the transcript { } was {X} was not requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed, are appended hereto.

I further certify that I have no disqualifying interest, personal or financial, in any party.

Witness my hand this 20th day of May, 2015.

KARLA MEYER BAEZ, CSR NO. 4506

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

ILLUMINA, INC.,	)	Opposition No. 91194218 (parent)
	)	Ser. No. 77/768176
Opposer/Petitioner,	)	
	)	Opposition No. 91194219
-v-	)	Ser. No. 77/775316
	)	
MERIDIAN BIOSCIENCE, INC.,	)	Cancellation No. 92053479
	)	Reg. No. 3887164
Applicant/Registrant.	)	
	)	Cancellation No. 92053482
	)	Reg. No. 3868081
	)	

DECLARATION OF PAUL A. GRANATO, PH. D., IN SUPPORT OF APPLICANT / REGISTRANT'S MEMORANDUM IN OPPOSITION TO OPPOSER / PETITIONER'S MOTION FOR SUMMARY JUDGMENT

I, Paul A. Granato, hereby state and declare as follows:

1. My name is Paul A. Granato, I am over eighteen (18) years of age, and I have personal knowledge of the facts stated in this Declaration.

2. In 1967, I earned a Bachelors degree in biology from LeMoyne College in Syracuse, New York. In 1971, I earned my doctorate in Microbiology from Syracuse University in Syracuse, New York. I was a post-doctoral fellow in Clinical Microbiology from 1971 to 1973 at Columbia University, College of Physicians and Surgeons, in New York, New York.

3. I am currently the Director of Microbiology at the Laboratory Alliance of Central New York, located in Liverpool, New York. As Director of Microbiology, I am responsible for the operational activities and diagnostic testing for this full service laboratory that provides diagnostic testing in the areas of bacteriology, virology, mycology, parasitology, and myco-bacteriology. Importantly, my responsibilities also include the evaluation and implementation of new molecular PCR and microarray technologies for the diagnosis of infectious diseases. These services are provided 24 hours each day with a staff of 40 FTE.

4. I am also a professor of pathology at SUNY Upstate Medical University.

5. Among other duties, I am involved in the purchasing decisions for clinical diagnostics products and other products in my laboratory. My laboratory is a consumer of Meridian's clinical diagnostics products, including Meridian's ILLUMIGENE molecular diagnostic tests.

6. In the past, among other positions, I have served as Clinical Microbiologist in the Crouse Irving Memorial Hospital in Syracuse, New York (August 1986 – June 1993); Chief of Microbiology of the V.A. Medical Center in Syracuse, New York (September 1976 – August 1986); and Assistant Clinical Professor in the Department of Laboratory Medicine at the University of Connecticut Medical School in Farmington, Connecticut (September 1973-September 1976).

7. Through my current and past work experiences, I am very familiar with the processes by which clinical laboratories identify the need for products, select products to purchase, and arrange contracts for purchase prices with the companies who market the products. The general purchasing process and the types of people or departments involved are similar in the various laboratories in which I have worked and in others that I have observed.

Purchasing Products in a Clinical Diagnostics Laboratory

8. The typical situation which I describe below is true of my current laboratory and the other laboratories in which I have worked.

9. There are typically several specializations within a Clinical Diagnostics Laboratory, including for example Microbiology, Chemistry, Hematology, Special Chemistry, and/or others. Each department has a manager or supervisor.

10. The manager/supervisor of each department may have products that he or she identifies as needed for the department's work. The manager/supervisor gives the product description, or often a catalog number and supplier name, to a purchasing agent or the laboratory's purchasing department. The purchasing agent or purchasing department will locate a supplier for the product and place an order under a pre-negotiated contract with the supplier

that includes set pricing. Sometimes, for products that are known to be needed in a certain quantity on a regular basis, standing orders will be set up without the need for separate purchase orders that would otherwise be required each week or each month. Again, such products are covered by a pre-negotiated contract that includes pricing.

11. Purchasing departments or purchasing agents are typically responsible for selecting manufacturers and distributors and negotiating contracts with them, under which individual orders for products are placed. The managers/supervisors of the laboratory departments request the products that are needed, but the purchasing personnel of the laboratory typically choose the vendor to supply the products and set up the contracts, if more than one vendor provides the same product.

12. When there is more than one vendor of the type of product that a purchasing agent needs to procure, he or she will usually solicit bids from the multiple vendors and select the best overall option. The selection is largely based on price, but other factors in the decision may include responsibility and reliability of the vendor, from reputation or past experience.

13. Laboratory managers/supervisors and purchasing departments or agents are often aware of vendors and their available product lines from being contacted personally by sales representatives from the vendors. In this context, Meridian and Illumina are the "vendors" or "suppliers."

The Sophistication and Attention Level of Purchasers in a Clinical Laboratory

14. Everyone in a Clinical Diagnostics Laboratory who is responsible for requesting or purchasing products is well-educated and highly sophisticated.

15. The laboratory managers/supervisors typically have specialized post-grad scientific education, and are experienced with requesting products for the laboratory and familiar with the products that are available and their sources.

16. The very great majority purchasing agents of Clinical Diagnostics Laboratories have a college education and specialize in sourcing products, soliciting bids, negotiating pricing

contracts, and purchasing products. They are typically experienced in purchasing for medical institutions and are intimately familiar with the manufacturers and suppliers in the market and the products that they supply.

17. In the field of Microbiology within a Clinical Diagnostics Laboratory, the managers/supervisors and purchasing agents are usually very familiar with what diagnostic tests are available for various infectious diseases and what companies provide or offer those tests. It is their job to know, and although some of the product names are complex, and although some of the product names are similar to one another, they are repeated with enough frequency that they are thoroughly learned.

18. For department managers/supervisors, it is a job requirement to be well informed about the products available, the names of those products, and the companies that make them.

19. Both the laboratory managers/supervisors and the purchasing agents in a Clinical Diagnostics Laboratory pay close attention to the products that they buy and the sources of those products. To order a product, they must first know the source(s) of it, so that they can purchase it under the pre-negotiated contract or solicit one or more bids for a new contract. They pay attention to these sources and product names.

The Significance of Company Names and Full Product Names in a Clinical Laboratory.

20. Personnel at Clinical Diagnostics Laboratories, including the department managers/supervisors and purchasing agents discussed above, are accustomed to the names of different medical products sounding similar to one another, or sharing identical beginnings but different endings, or *vice versa*. Naming conventions such as these are not uncommon in the industry.

21. The people who impact purchasing decisions pay close attention to the full words in a product name, including the endings of the words, and also have a keen awareness of the company names that are suppliers of the products they purchase. When they are requesting or ordering products, they focus on and use the name of the supplier of the product as well as the

full name of the product itself. They know that mistakes in medical supplies orders are potentially very costly, and they proceed carefully and according to the purchasing process, not impulsively or in a great hurry.

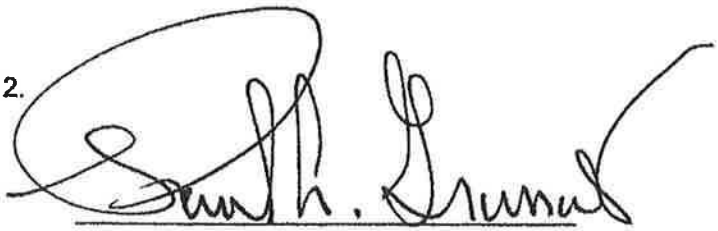
22. Without the name of the supplier, purchasing agents could not order the products under the negotiated contract. To make orders, they first locate the supplier who offers the product that has been requested, and then place the order. If they encounter a product name without an accompanying name of the supplier of the product, they will look up the name of the supplier and ensure that it is the right company. The contracts negotiated between the laboratory and the supplier are negotiated carefully and cover the particular products that the supplier has available, assigning pricing to each. Products are then ordered pursuant to these negotiated contracts, with the name of the supplier firmly identified and in mind at the time that products are ordered.

23. By way of example, if someone working in my Microbiology Lab needs a test for *Clostridium difficile*, and does not already have one, he may research available options or consult with marketing material received from vendors. If, for example, he wants to order and use the ILLUMIGENE product, he will contact his purchasing agent and request that the ILLUMIGENE product be ordered. If the Microbiology Lab does not currently order the ILLUMIGENE product, the purchasing agent will look up the vendor that supplies that product. When the purchasing agent determines that Meridian is the vendor, the purchasing agent will check to see whether the Laboratory has an existing vendor contract with Meridian. Finding that we do, the purchasing agent will then arrange for the purchase of ILLUMIGENE test kits from Meridian. Unless another vendor also offers an ILLUMIGENE or similar-sounding product for

the same purpose – here, to test for the presence of *Clostridium difficile* – the purchasing agent will not be confused as to what she is ordering and/or who she should be ordering it from.

Pursuant to 37 C.F.R. § 2.20, the undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting therefrom, declares that all statements made of my own knowledge are true; and all statements made on information and belief are believed to be true.

Executed on June 29, 2012.



Paul A. Granato, Ph.D., DABMM, FAAM

ILLINC.266M TRADEMARK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc.,	Opposition No.: 91194218
Opposer,	
v.	
Meridian Bioscience, Inc.,	
Applicant.	

REBUTTAL DECLARATION OF NAOMI O'GRADY

I, Naomi O'Grady, declare as follows:

1. I have personal knowledge of the matters set forth herein and if called upon to testify, I could and would competently testify thereto.

Illumina's Products are Marketed to a Broad Range of Customers

2. In Paragraph 15 of his declaration, Mr. Kozak asserts "[g]iven Meridian's marketing and sales strategy and the strict separation of the clinical and research disciplines within any given hospital lab or reference lab, the relevant consumers on the research side of such labs – i.e. the consumers of Illumina's product – probably have very little if any familiarity with Meridian. Conversely, Meridian's relevant consumers on the clinical diagnostic side of such labs probably have very little if any familiarity with Illumina." I disagree with Mr. Kozak's assertion.

3. First, as explained elsewhere in this declaration, Illumina's customers are not limited to research labs. Instead, since at least 2007, Illumina's products have been used in clinical diagnostics labs.

4. Second, as also explained elsewhere in this declaration, clinical diagnostics labs

are not always separated by application segment, as Mr. Kozak states in Paragraphs 30 and 31 of his declaration.

5. Third, as explained below, Illumina's marketing efforts reach all aspects of the molecular biology industry, including both research labs and clinical diagnostics labs (e.g., molecular pathology), and across all of the application segments that Mr. Kozak identifies in Paragraph 7 of his declaration.

6. Illumina's marketing efforts have such a broad reach because Illumina focuses its marketing efforts on the broadest category of diagnostic customers. More specifically, Illumina begins its marketing process by targeting Molecular Pathologists as a whole, as opposed to focusing on a specific customer group. These broad marketing efforts are accomplished, in part, by utilizing pre-compiled customer lists of Molecular Pathologists.

7. Molecular pathology is focused on the study and diagnosis of disease through the examination and detection of molecules within organs, tissues or bodily fluids. It includes the application of molecular and genetic approaches to the diagnosis and classification of human diseases (both genetic and infectious diseases), the design and validation of predictive biomarkers for treatment response and disease progression, and the susceptibility of individuals of different genetic constitution to develop disorders. Molecular pathology is commonly used in diagnosis of cancer and other genetic diseases as well as infectious diseases, and both Meridian's and Illumina's products fall within the molecular pathology category. Thus, when the products are used for the purpose of diagnosing patients, they both also fall within the sub-category of molecular diagnostics.

8. There are a limited number of entities that rent compiled lists of potential customers in the molecular pathology space. For example, the Association of Molecular Pathology ("AMP") and the College of American Pathologists ("CAP") rent such lists. It is common practice for manufacturers of molecular pathology products to purchase these lists and focus marketing efforts based on the lists.

9. Illumina rents customer lists from one or more of the aforementioned associations, and it sends marketing materials covering the whole range of its products to the potential customers indicated on the list. Under this umbrella approach to marketing, there is no consideration given to any particular customer's specialty (assuming a customer even has a specialty). As a result, any laboratory that performs services within the context of molecular pathology is likely to receive Illumina's marketing materials.

Lab Developed Tests ("LDTs") are Commonly Developed By Clinical Diagnostic Labs

10. Throughout his declaration, Mr. Kozak suggests that Illumina's products have only been used in research labs and not in clinical diagnostics labs. This is incorrect. In addition to the fact that Illumina has received FDA clearance for various IVD devices, Illumina's RUO-labelled products—including its MiSeq®, HiSeq®, NextSeq®, Bead Array Reader, iScan®, and BeadXpress® instruments and their associated consumables —while marketed as RUO ("Research Use Only") products, have routinely been purchased by labs and other customers that subsequently have promoted their products as LDTs since at least 2007 (or, for some of the aforementioned products, their date of introduction if later).

11. Although those instruments and consumables are not the sole components of the LDT, they constitute a substantial aspect of the LDT because they are what actually analyzes and identifies the genetic material at issue.

12. For that reason, I disagree with Mr. Kozak's bolt manufacturer analogy in Paragraph 24 of his declaration. Illumina's devices are not analogous to a mere commodity such as a bolt. Instead, they are more analogous to the engine.

13. Illumina's instruments (e.g., MiSeq®, HiSeq®, NextSeq®, Bead Array Reader, iScan®, BeadXpress®) may be used by LDT developers to detect DNA. While the technology is different, Meridian's ILLUMIPRO instruments also detect DNA. In addition, the LDT developers that use Illumina's instruments also often use Illumina's reagents in sample

preparation assays which are read by the Illumina instrument. Similarly, Meridian provides ILLUMEGENE assays that prepare a sample to be read by its ILLUMIPRO instruments.

14. Further, LDTs are commonly developed by clinical diagnostic labs, which also use IVD products.

15. In fact, LDTs are commonly used to diagnose patients. Often, the same clinicians in a lab are using both LDTs and IVDs. This is because the rapidly evolving needs at the diagnostics level vastly outpace the process of becoming an FDA-cleared or approved IVD. As an illustration, when a new disease or new strain of a disease is discovered, the need to diagnose patients begins immediately, whereas the ability to receive FDA clearance or approval as an IVD lags behind. LDTs are critical to keep pace with medical needs.

Illumina Has a Presence in the Infectious Disease Market

16. Throughout his declaration, Mr. Kozak repeats that only Meridian, not Illumina, has any presence in the infectious disease market. Further, Mr. Kozak states that Meridian's products are used in detecting pathogens, while Illumina's products are limited to tests in *human* genetics. Both assertions in reference to Illumina are inaccurate.

17. Since at least 2007, Illumina's products could be utilized specifically for work with infectious diseases. In particular, BeadXpress® could be used to identify diseases, whether genetic and inherited or infectious diseases, based on the DNA make-up of the disease.

18. In 2007, Illumina collaborated with the University of Maryland School of Medicine in connection with a grant received by the Gates Foundation to use the VeraCode® and BeadXpress® platform to detect the microbial pathogens that contribute to diarrheal disease (i.e., infectious diseases, including *C. difficile*).

19. In 2009, Illumina explored the use of its BeadXpress® platform with EraGen to identify various flu causing viruses/bacteria by the DNA make-up of the same.

20. To encourage development of diagnostics related to complex diseases including infectious diseases, in 2010, Illumina created the VeraCode® Assay Design Challenge.

Illumina granted an award to the Royal Women's Hospital in Melbourne for the development of diagnosis methods for infectious urethritis (Exhibit 1).

21. In addition, in 2010, Illumina had development programs for tests related to detecting multi-drug resistant organisms (including and a viral transplant panel to detect infectious diseases) (Exhibits 2 and 3). Both of these development programs were presented at Illumina marketing external seminar series (Exhibits 4 and 5).

22. In January 2011, Illumina acquired Epicentre Biotechnologies Corporation. Epicentre manufactures specialty enzymes and biological preparations for use in molecular biology research and medical diagnostics. For example, Epicentre markets the QuickExtract™ Bacterial DNA Extraction Kit. This kit provides a simple method for extracting DNA for use with a variety of applications such as creation of lab-developed tests, and has been tested with a range of bacteria, including *Streptococcal* bacteria, *E. Coli*, and *Salmonella typhimurium*, which are infectious diseases. Accordingly, this kit is useful across a number of fields, including in life-sciences research, applied markets, and the molecular diagnostics market and has been bought by a number of our clinical diagnostic lab customers.

23. In 2011, Illumina collaborated with Siemens Healthcare to develop an assay to detect HIV. In fact, Illumina built a Biosafety Level 2 (BSL-2) lab for the Research and Development group at this time to be able to handle blood samples received through Illumina's work with Siemens. A BSL-2 lab is a special lab designed to contain biological agents in an enclosed facility. In the United States, the Centers for Disease Control and Prevention specify the required levels. A level 2 facility is required for work involving agents of moderate potential hazard and requires that laboratory personnel receive specific training in handling pathogenic agents and be directed by scientists with advanced training. Companies build these types of labs, and Illumina did build its lab, to be able to work with infectious diseases.

24. In November 2011, Illumina collaborated with Siemens Healthcare Diagnostics to make Siemens' molecular HIV tests compatible with Illumina's MiSeq® platform and to develop

additional sequencing-based infectious disease assays for the clinical diagnostics market. Through its venture with Siemens, Illumina saw additional adoption of its next generation sequencing (NGS) technology in the clinical diagnostics market.

25. Further to promotional and marketing activities mentioned in my previous declaration, both Illumina and Meridian also attend the American Society for Microbiology events, in 2013 and 2014 both Illumina and Meridian have been Exhibitors at the American Society for Microbiology annual meeting. (Exhibit 6).

26. Illumina's products are also used in connection with infectious disease by virtue of molecular epidemiology, which includes identifying the genome of infectious diseases (i.e., the genome of the disease causing agents such as bacteria and viruses) affecting human populations for infectious disease control. For example, hospitals have created assays that utilize Illumina's MiSeq® for infectious disease control by identifying how the disease has spread within the hospital.

27. Due to the significant impact Illumina's products have in connection with infectious disease, Illumina formally created its Microbiology Group in 2010. The purpose of this group was to build on the prior work and continue to expand and further develop the uses of Illumina's technology for infectious disease.

28. In 2014, Illumina entered into a collaboration with BioMerieux to develop applications for microbiology sequencing technologies. Utilizing Illumina's MiSeq® next-generation sequencing system in conjunction with BioMerieux's culture collection of more than 80,000 references for infectious diseases, the companies plan to jointly develop a pathogen genome database. (Exhibits 7 and 8). The end result of this project will be an accurate, fast, and accessible solution for medical providers to detect infectious disease and thereby both contain endemics and avoid transmission of infectious agents. Simply put, this product will be a sequencing solution dedicated solely to detection of infectious diseases.

29. In addition to the BioMerieux collaboration, Illumina's MiSeq® next-generation

sequencing system has already had significant success in the clinical microbiology (i.e., infectious disease) space. Part of this success is due to the fact that hospital infection control has been one of the major emerging issues in recent history. As an illustration, Methicillin-resistant *Staphylococcus aureus* (commonly known as MRSA) is commonly acquired during a patient's stay at a hospital. MRSA can be life threatening because of its resistance to antibiotics and ease of transmission. Before its collaboration with BioMerieux, Illumina had development programs for tests related to MRSA (Exhibits 4 and 5).

30. When an outbreak is suspected, hospitals will commonly collect samples from patients and the environment, and send them to a clinical microbiology lab for testing. Clinical microbiology labs will then use Illumina's sequencing products to analyze the samples, compare them to others, and inform the hospitals of whether or not there has been an infectious disease outbreak.

Overlap of Infectious Disease with Other Areas of Diagnostics

31. In his declaration, Mr. Kozak suggests that infectious disease is always separate and distinct from other types of diagnostic work. I disagree. I personally know of at least five individuals who run labs that perform infectious diseases diagnostics along with other areas of diagnostics such as diagnostics related to genetic health:

- Dr. Greg Tsongalis is the Director of Molecular Pathology and the Co-Director of the Translational Research Program and Pathology Shared Resource at Dartmouth College. His practice focuses on Molecular Diagnostics for Infectious Disease, Molecular Genetics, Molecular Oncology and Pharmacogenomics;
- Dr. Karen Weck is the Director of the Molecular Genetics Laboratory at the University of North Carolina School of Medicine. Her work deals with both the diagnosis of infectious diseases and other diseases such as genetic diseases;
- Dr. Wayne Grody is the Director of the Molecular Diagnostics Laboratory at UCLA. His lab offers DNA-based tests for diagnosis of a wide variety of genetic, infectious,

and neoplastic diseases, as well as bone marrow engraftment, patient specimen identification and paternity testing by DNA fingerprinting;

- Dr. Andrea Ferreira-Gonzalez is the Chair of the Division of Molecular Diagnostics in the Department of Pathology and the director of the Molecular Diagnostics Laboratory at the Virginia Commonwealth University Health System. She works in the field of molecular diagnostics in the area of genetics, oncology, personalized medicine, pharmacogenetics and infectious diseases.

- Dr. Stephen Young, is the Scientific Director of Infectious Disease at TriCore Reference Laboratories and a Professor in the Department of Pathology at the University of New Mexico. He has purchased an Illumina Bead Array reader specifically for cytogenetics use. Dr. Young's lab also focuses on the diagnosis of infectious diseases such as C. difficile, Adenovirus, HMPV, RSV, Rhinovirus, and various Influenza strains.

- Both Dr. Tsongalis and Dr. Ferreira-Gonzales were former Association for Molecular Pathology (AMP) presidents. The primary task of an AMP president is to convey the essential role of molecular pathology to the broader medical community, patients, the public and the government which, in turn, will promote the highest quality of molecular diagnostics to improve patient care.

32. Moreover, further to the previous section, the five labs mentioned above perform their services using a combination of LDTs and IVDs.

Pricing

33. Mr. Kozak points out that Illumina's products, such as the BeadXPress® and MiSeqDx® cost $95,000 and $125,000 respectively. Illumina, however, has programs to place its instruments in labs at no upfront cost through the use of leasing and reagent rental models and evaluation to purchase agreements.

34. Further, the assays (or tests) sold to be used with Illumina's instruments have a similar cost to Meridian. One benefit of Illumina's technology is it replaces iterative single

analyte assays with multiplexed analysis leading to cost, labor and workflow efficiencies. For example, Illumina's BeadXPress® tests cost in the range of mere pennies to $40 per sample and when multiplexed cost $0.50 to <$1 per analyte. In addition, a 15-gene DNA sequencing panel, with a cost of $200 per sample, yields a cost per gene of $13, which equates to less than a penny per nucleotide.

Illumina's Affiliation with Other Companies

35. Illumina's name is often used in the marketing materials of various third parties including reference or clinical diagnostic labs. As an illustration, Illumina developed a collaborative service arrangement called the Illumina Certified Service Provider (CSPro). In effect, this arrangement allows such labs to display the Illumina name and logos, in conjunction with their own, so customers can be sure they are receiving the industry-leading data quality and service they have come to expect from Illumina. There are no less than 34 labs in North America that display the Illumina certification in connection with the services they provide.

36. Once a lab has received its certification from Illumina, Illumina CSPro laboratories receive materials such as co-branded CSPro flyers with the laboratory's contact information, logo, and description, lab signs, polo shirts for laboratory staff, and Illumina product literature. Furthermore, co-marketing such as a feature article in Illumina's iCommunity e-newsletter, a co-promotional package at a trade show, email blasts, additional technical training, sponsorships, open house, and workshops are available to the partnered lab.

Illumina's Registrations and Meridian's Applications/Registrations

37. In Paragraph 17 of his declaration, Dr. Elagin asserts Illumina's recitations are "extremely vague." I disagree; Illumina's recitations are not vague.

38. In Paragraph 11 of his declaration, Dr. Elagin discusses the recitation of goods in Meridian's ILLUMIGENE and its ILLUMIGENE MOLECULAR SIMPLIFIED & design registrations. The recitation is "Diagnostic kits consisting of molecular assays for use in disease testing and treatment of gastrointestinal, viral, urinary, respiratory and infectious diseases." Dr.

Elagin states that one would interpret this "to mean an amplification/detection test for microbial, viral, or other disease-causing agent." I disagree with this statement. To the contrary, there are gastrointestinal, urinary, and respiratory diseases that are not caused by a microbial, viral, or other disease-causing agent. These would include diseases that are inherited, have a genetic susceptibility, and/or are acquired through somatic genetic mutations, such as cystic fibrosis, chronic obstructive pulmonary disease (COPD), stomach cancer, bladder cancer, colon cancer and lung cancer.

39. In Paragraph 14 of his declaration, Dr. Elagin states that one "would recognize that nothing in Meridian's trademark registrations and applications refers to any good or service that would use "random array technology." I disagree with this statement with respect to the ILLUMIGENE registrations. More specifically, molecular assays for use in disease testing and treatment of gastrointestinal, viral, urinary, respiratory and infectious diseases could be used with microarray or random array technology.

40. In Paragraph 14 of his declaration, Dr. Elagin discusses the recitation of goods in Illumina's Registration No. 2471539. The recitation is "Developing, to the order and specification of others, biological and/or chemical sensing systems which use random array technology to identify inorganic and organic molecules, compounds, and substances." Dr. Elagin then recites his "understanding [] that the term 'random' implies that a system has random access for a sample input, and 'array' means microarray technology." Dr. Elagin is wrong regarding his understanding of random. Instead, the word "random" in this context means that the collection of microscopic regions used in microarray technology are arranged randomly, rather than in a prearranged configuration.

41. In Paragraph 14, Dr. Elagin also states that microarray technology "is completely different from the ILLUMIGENE technology which utilizes a single analyte amplification and detection by turbidimetry." With respect to the "single analyte" portion of his statement, there is nothing in the ILLUMIGENE recitations that limits the described goods to detection of a single

analyte. Moreover, although microarray technology is often used for multi-analyte analysis, it could also be used to detect a single analyte as well. With respect to the "turbidimetry" portion of his statement, there is nothing in the ILLUMIGENE recitations that limits the described goods to the use of turbidimetry.

42. In Paragraph 14, Dr. Elagin states that "ILLUMINA-branded products are in a different field of endeavor with different consumers – consumers who are looking not for 'ready-made' IVD tests and locked IVD software on readers of those tests, but rather for open-platform research equipment that customers can tweak – certainly RUO products, not IVD products." This statement is incorrect because ILLUMINA-branded products are not only bought by consumers looking for open-platform research equipment. Rather, Illumina-branded products are also purchased by labs that develop diagnostic tests. And, as explained in my and Ms. Possemato's original declarations in this matter, Illumina sells FDA-cleared IVD products. One of those IVD products, the MiSeqDx is referred to as an open platform and is sold with a kit called the Universal Kit; this shows that open platform systems and consumables can be IVDs and can also be used by labs for diagnostic use.

43. As explained above, since at least 2007, Illumina's products have been selected by CLIA-certified labs for use in LDTs. Consumers that create LDTs are often also purchasers of IVD products.

44. For this same reason, Dr. Elagin is incorrect when he states in Paragraph 14 that "the 'random array technology' described in this recitation implies such open-platform research equipment that is used by consumers separate and distinct from the ready-made 'kits' identified in Meridian's ILLUMIGENE recitations." Nothing in the recitation in Illumina's Registration No. 2471539 says that the developed goods would only be used for research. Instead, the goods are often used by labs that perform lab developed tests (LDTs). In addition, nothing in the recitation in Illumina's Registration No. 2471539 says that the recitation would only be used for open-platform use. Instead the recitation could be for targeted applications.

45. Dr. Elagin also addresses Illumina's Registration No. 2756703, which recites "Scientific equipment and instruments, namely scanners, hybridization stations and fluidics delivery and computer systems sold as a unit and cassettes containing molecular sensing optical fiber bundles for analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 Dalton." In Paragraph 16, he states that this recitation "describes types of equipment that are used in scientific research ...." To the extent Dr. Elagin is suggesting that the recitation describes types of equipment that are ***only*** used in scientific research, he is wrong. To the contrary, the goods described in this recitation could be purchased by a diagnostic laboratory for use in LDTs and have been purchased extensively by customers who develop LDTs.

46. In Paragraph 16, Dr. Elagin also states that "the two types of tests have critically different functions and contexts, with different applications and consumers: those who would be interested in a single target detection in a closed system for human in vitro diagnostics testing (Meridian's ILLUMIGENE product) on the one hand versus those seeking to identify multiple analytes in a high throughput screening context (Illumina's sequencing DNA, genotyping, gene expression profiling and high through-put screening' products, for instance)." To the extent the first portion of this statement refers to the IILUMIGENE recitations, it is wrong because nothing in that recitation limits the goods to "single target detection." Second, to the extent Dr. Elagin is attempting to limit Illumina's recitation to "high through-put screening" he is incorrect because the recitation includes more, such as analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing DNA, genotyping, and gene expression profiling. In any event, despite any differences in the functions of the two types of tests, those different functions do not necessarily imply different customers. This is because the goods recited in Illumina's Registration No. 2756703 could be used in LDTs by customers that also use IVDs that test for a single target.

47. In Paragraph 14, Dr. Elagin also states "for example, an individual using an Illumina product for 'high through-put screening' is not attempting to identify a single pathogen in

a human sample. Rather, that individual is conducting research on a large scale attempting to identify a number of different genetic variations that might be present in a person's DNA." This statement is both wrong and misleading. Dr. Elagin's statement is misleading because he refers only to high through-put screening when he states that the user "is not attempting to identify a single pathogen in a human sample." He ignores the other aspects of Illumina's registration, which refers to "analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing DNA, genotyping, and gene expression profiling." He also misleadingly suggests that the product would only be analyzing a human sample. To the contrary, these methods have been used to identify a single pathogen in a human or non-human (such as animal, bacterial, or viral) sample.

48. In Paragraph 18, Dr. Elagin states that Illumina's recitations "describe the detailed study and characterization of human genetic material in scientific research." This is incorrect. The two recitations that I have addressed in this declaration are not limited to goods that are only ever used to conduct research. Instead, they can and have been selected by diagnostic laboratories for use in LDTs. Second, the goods are not limited to use with human genetic material. Instead, they can and are used with non-human material such as animal, bacterial, or viral samples. And contrary to Dr. Elagin's other statement in Paragraph 14 – that "the consumers interested in such goods are dramatically different ..." – consumers for products to be used in an LDT are often also consumers for IVD products. And the consumers of products that detect infectious diseases are also consumers of products that detect other diseases, including genetic diseases.

49. To be clear, even though the technology may be different, both Illumina's products and Meridian's ILLUMIGENE and ILLUMIPRO products can be used to identify infectious disease by detecting genetic sequences that match the particular disease.

50. In Paragraph 24 of his declaration, Dr. Elagin states that all of Illumina's registrations "specify that the goods and services will be used in scientific research, human

genetic sequencing or genotyping, and specifically by using microarrays." This is incorrect. As I explained above, the two ILLUMINA registrations that I reference above are not limited to research use. They are also not limited to genetic sequencing or genotyping. Further, they are not limited to the human genome and could be used and are used for non-human genomes, e.g. for viral or bacterial genomes.

51. In Paragraph 25 of his declaration, Dr. Elagin attempts to distinguish Illumina's and Meridian's customers. In so doing, and for the reasons described above, he mischaracterizes the goods and services recited in Illumina's Registration Nos. 2471539 and 2756703. He also states that "the consumers of 'diagnostic kits' and 'diagnostic machines' are treating/clinical physicians looking for an inexpensive and quick way to confirm or deny the presence of a particular bacteria, fungus, or virus." This is misleading in a few ways. First, Meridian's own package inserts for its ILLUMIGENE and ILLUMIPRO products indicate that the use is intended for "hospital, reference or state laboratory settings," and "not intended for point-of-care use". (Exhibit 9). Second, even if true, it is not true of all diagnostic kits and machines. Diagnostic kits and machines are used in various settings, including clinical diagnostic labs that purchase products to be used in LDTs and also purchase IVD products. In addition diagnostic kits and machines can be used for other and more complex uses, included for analyzing human genetics. In addition, Dr. Elagin mischaracterizes the questions that a consumer of Illumina's products may ask. Contrary to Dr. Elagin's statements, consumers use Illumina's products in LDTs to answer the question "Does this patient have the disease X?"

52. In Paragraph 27 of his declaration, Dr. Elagin separately states that (1) "in 2008, Illumina's products had zero presence inside a Clinical Diagnostic or Microbiology Laboratory"; (2) "in 2008 through 2009, Illumina's products and services were focused on research applications as 'Research Use Only' ('RUO') products and were not cleared by the FDA for 'In Vitro Diagnostic' use ('IVD')"; and (3) "these RUO products are used by academic laboratories, medical centers for research purposes, government research entities, large pharmaceutical

companies who do substantial research, and research laboratories, *not* the clinical diagnostic laboratories. In general, Illumina operated in the research market ...."

53. Although it is true that Illumina did not have an IVD product at this time, these statements contain many inaccuracies. As stated above, Illumina was not absent from clinical diagnostic laboratories during this time because its products were selected by many diagnostic labs as part of LDTs. Many of such labs purchase RUO products to use in LDTs and also purchase IVD products. In addition, in 2008, Illumina had a marketing presence in the clinical laboratory and microbiology laboratory industries. This marketing presence was achieved by attendance at tradeshows such as AMP as well as other marketing activities.

54. In Paragraph 28 of his declaration, Dr. Elagin states that "in a small number of medical institutions, or in much larger and well-funded institutions, researchers in the research laboratory side do work that would be considered, in one sense of the word 'diagnostics,' but it is not through the use of IVD clinical diagnostic products...rather in this small subset of laboratories researchers create their own diagnostic assays from RUO parts and components..." First, Dr. Elagin has mischaracterized the market. What Dr. Elagin is referring to when he states that researchers create their own diagnostic assays from RUO products is what I have been referring to as LDTs or "lab developed tests." It is not a small number of medical institutions or only larger more well-funded institutions or only a small subset of laboratories that conduct LDTs. To the contrary, many clinical diagnostic labs develop and market LDTs. As stated previously, in addition to using Illumina's products to develop LDTs, these institutions, including clinical diagnostic labs, also use IVD products such as Meridian's ILLUMIGENE and ILLUMIPRO products and Illumina's IVD diagnostic products. In addition, persons that buy Illumina's products to develop and market in LDTs are providing diagnostic services. Therefore, characterizing all persons that use Illumina's products as "researchers" is incorrect.

55. In Paragraph 30 of his Declaration, Dr. Elagin states that "[T]he only 'diagnostic

product or service' in this LDT environment, necessarily due to regulations, is the test report from the laboratory." This is incorrect, LDTs themselves are diagnostic services.

56. In Paragraph 37 of his declaration, Dr. Elagin discusses the VeraCode® Genotyping Test on the BeadXpress® platform, which was based on nucleic acid amplification and solid-phase hybridization technology to detect single nucleotide polymorphisms (SNPs). Dr. Elagin incorrectly implies that the platform was limited to the detection of human inherited disease and "it has nothing to do with infectious disease or microbiology..." Instead the nucleic acid amplification and solid-phase hybridization technology has been used in an infectious disease and microbiology setting. For example, Illumina partnered with the University of Maryland School of Medicine in connection with a grant received by the Gates Foundation to use the VeraCode® and BeadXpress® platform to detect the microbial pathogens that contribute to diarrheal disease (i.e., infectious diseases, including C. difficile).

57. In Paragraphs 39 and 42 of his declaration, Dr. Elagin states that "analyzing human genetics is a totally separate scientific field from detecting infectious diseases." I disagree with this statement. Instead, the fields are closely related. Both involve detecting nucleic acids, and the same scientific methods are often used to detect human nucleic acids and the nucleic acids of a microorganism. In fact, the genetic blue print of both humans and microorganisms are made from the same building blocks – i.e., DNA and/or RNA represented as strings of nucleotide bases. This means the type of chemistry, tools, and techniques used to analyze human nucleic acids can and are often used to analyze the nucleic acids in a microbial organism such as the nucleic acids of infectious diseases.

58. In Paragraph 40 of his declaration, Dr. Elagin discusses Illumina's Cystic Fibrosis IVD products. He states that "the consumer of such a product is analyzing what causes human inherited diseases (cystic fibrosis in this case), and it has nothing to do with the analysis that is conducted in infectious disease or microbiology laboratories where the technician is trying to perform a specific test quickly in order to identify what is making a patient sick so that he can be

treated." Dr. Elagin is incorrect. Illumina's Cystic Fibrosis clinical sequencing assay is an IVD used to identify what is making a patient sick so that he can be treated. In addition, Dr. Elagin states that Ilumina's only current IVD products are its two Cystic Fibrosis IVD products. That is incorrect. There are three ready-to-use cleared FDA tests currently available. The two Cystic Fibrosis tests mentioned in Dr. Elagin's declaration, but also the MiSeqDx® Universal Kit. In addition, all these are run on the Illumina MiSeqDx®, which also is regulated by FDA as an IVD platform.

59. Illumina's MiSeqDx® Universal Kit is an open platform test – i.e., a validated, FDA-cleared kit enabling molecular diagnostic laboratories to design their own assays for use on the MiSeqDx® instrument. Designed specifically for the clinical laboratory environment, the MiSeqDx® instrument offers a small footprint, an easy-to-follow workflow, and data output tailored to the needs of clinical labs. In addition, the integrated software enables sample tracking, user traceability, and results interpretation. Taking advantage of proven Illumina sequencing technology, the MiSeqDx® instrument provides accurate, reliable screening, and diagnostic testing.

60. In Paragraph 41 of his Declaration, Dr. Elagin states that Meridian's ILLUMIPRO machines cannot be used with any of Illumina's products. This is incorrect. Meridian previously sourced an Illumina product for use with its ILLUMIGENE and ILLUMIPRO goods. That product called DisplaceAce was manufactured by a company that Illumina acquired in 2011 called Epicentre.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration

resulting therefrom, declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Executed this 8th day of April 2015 at San Diego, California

Naomi O'Grady

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040715

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing Rebuttal Declaration of Naomi O'Grady upon Applicant's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on April 8, 2015, addressed as follows:

J. Michael Hurst
Keating Muething & Klekamp PLL
One East 4th Street
Suite 1400
Cincinnati, OH 45202

Sarah Beno Couvillion

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc., Opposer, v. Meridian Bioscience, Inc., Applicant.	Opposition No. 91194218 (parent) Serial No.: 77/768176 Mark: ILLUMIPRO Opposition No. 91194219 Serial No.: 77/775316 Mark: ILLUMIPRO-10

OPPOSER'S RESPONSES AND OBJECTIONS TO APPLICANT'S SECOND SET OF INTERROGATORIES TO OPPOSER

Pursuant to Fed.R.Civ.P. 33, Illumina, Inc., ("Opposer"), hereby serves its responses and objections to, Meridian Bioscience, Inc.'s ("Applicant") First Set of Interrogatories to Opposer.

Preliminary Statement

These responses are made solely for the purpose of and in relation to this matter. Opposer has not fully completed it investigation, discovery, analysis, legal research, and preparation for trial in this matter. The responses contained herein are based only upon the information and documentation that is presently available and known to Opposer, and which has been identified as containing relevant information. It is possible that further investigation, discovery, analysis, legal research and/or preparation may result in the ascertainment of additional information or documentation, or provide additional meaning to known factual conclusions and legal contentions, all of which may result in modification of these responses. Accordingly, Opposer reserves the right, but does not assume the obligation, to modify its

responses herein based upon subsequently ascertained, identified, or developed information, facts and contentions.

Subject to the objections asserted herein, Opposer's responses are made in a good faith effort to reasonably respond to the Interrogatory based upon presently available information and documentation. These responses are provided without prejudice to Opposer's right to conduct further investigation, discovery, analysis, legal research and/or preparation, and shall not limit Opposer's right to utilize any additional evidence or documents that may be identified, discovered, or developed.

Specific objections to each separate Interrogatory are made on an individual basis in Opposer's responses below. In addition to the specific objections, Opposer makes certain general and continuing objections as well as objections to the definitions and instructions ("General Objections") to all of the Interrogatories. These General Objections are hereby incorporated by reference into the responses made with each Interrogatory. Opposer's response to each individual Interrogatory is submitted without prejudice to, and without waiving in any respect, any General Objections not expressly set forth in that response. Accordingly, the inclusion of any specific objection to an Interrogatory in any response below is neither intended as, nor in any way shall be deemed to be, a waiver of any General Objection or any other specific objection made herein or that may be asserted at a later date. In addition, the failure to include at this time any general or specific objection to an Interrogatory is neither intended as, nor shall in any way be deemed, a waiver of Opposer's right to assert that or any other objection at a later date.

General Objections

1. Opposer renews and incorporates by reference the General Objections set forth in Opposer's Responses and Objections to Applicant's First Set of Interrogatories to Opposer.

Objections to Definitions

1. Opposer renews and incorporates the Objections to Definition set forth in Opposer's Responses and Objections to Applicant's First Set of Interrogatories to Opposer.

Without waiving these objections, Opposer responds as follows:

Interrogatory No. 44:

Identify the date on which Opposer first sold or offered for sale (whichever is earlier) products or services under the ILLUMINA Marks that could be used in a clinical diagnostics lab of a hospital or reference laboratory.

Response:

Opposer incorporates its General Objections and its Objections to Definitions as if fully set forth herein. Opposer objects to this interrogatory as vague in that it is not clear what is meant by "could be used".

Subject to and without waiving its objections, Opposer responds that it first offered for sale services under the ILLUMINA Marks that could have been ordered by or delivered to individuals employed in a clinical diagnostics lab of a hospital or reference laboratory at least as early as December 5, 2006.

Interrogatory No. 45:

Identify the date on which Opposer first sold or first offered for sale (whichever is earlier) products or services under the ILLUMINA Marks that are approved by the U.S. Food and Drug Administration ("FDA") for in vitro diagnostic ("IVD") uses as further described here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm.

Response:

Opposer incorporates its General Objections and its Objections to Definitions as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it is not clear what is meant by "approved". The page from the FDA website listed in the interrogatory references "premarket approval" and "marketing clearance" amongst other types of approvals that could be relevant. Subject to and without waiving its objections, Opposer responds that it first offered for sale products approved by the U.S. Food and Drug Administration ("FDA") for in vitro diagnostic ("IVD") uses under the ILLUMINA Marks following immediately after the approval of its BeadXpress Multiplex Analysis System on April 28, 2010.

Respectfully submitted,

ILLUMINA, INC.

Date: **January 2, 2014**

James R. Menker

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing "OPPOSER'S RESPONSES AND OBJECTIONS TO APPLICANT'S FIRST SET OF INTERROGATORIES TO OPPOSER" was served on J. Michael Hurst of Keating Muething & Klekamp PLL, with an address at One East Fourth Street, Suite 1400, Cincinnati, OH 45202, via first class mail, postage prepaid, today January 2, 2014.

By: 
James R. Menker

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc., Opposer, v. Meridian Bioscience, Inc., Applicant.	Opposition No. 91194218 (parent) Serial No.: 77/768176 Mark: ILLUMIPRO Opposition No. 91194219 Serial No.: 77/775316 Mark: ILLUMIPRO-10

OPPOSER'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO APPLICANT'S FIRST SET OF INTERROGATORIES TO OPPOSER

Pursuant to Fed. R. Civ. P. 33 and subject to the General Objections and the Objections to Definitions and Instructions in Opposer's Responses and Objections to Applicant's First Set of Interrogatories to Opposer, Illumina, Inc. hereby serves following supplemental responses and objections to Applicant's First Set of Interrogatories to Opposer.

Interrogatory No. 10:

Identify all publications in which Opposer's products/services bearing the ILLUMINA Marks have been promoted in the United States.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "publications," "bearing" and "promoted" thus rendering the interrogatory unintelligible.

Subject to and without waiving its objections, Opposer answers that its website, <<http://www.illumina.com/publications/list.ilmn>>, includes a list of the numerous

publications in which researchers successfully used Opposer's products bearing Opposer's ILLUMINA Marks for a wide range of genetic analysis applications.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer provides the following list of print and electronic publications in which Opposer's products/services bearing the ILLUMINA Marks have been promoted in the United States:

Print Placements

American Journal of Human Genetics
Biotechniques
Cancer Cell
CAP Today
CELL
Cytogenetics & Genomic Research
Drug Discovery News
Genetic Engineering & Biotechnology News
Genome Research
Genome Technology
Human Molecular Genetics
Journal of Molecular Diagnostics
Methods (Cell)
Molecular Cell Microbe Magazine Nature
Nature
Nature Biotechnology
Nature Genetics
Nature Medicine
Nature Methods
Nature Reviews Cancer
Nature Reviews Genetics
Nature Reviews Microbiology
Plant Physiology
Science
Seed Today
Seed World
The Plant Cell
The Scientist

Electronic Placements

AACR Cancer Research

American Journal of Human Genetics
Animal Genetics
ASPB (American Society of Plant Biologists)
BioMCC
BioMed Central
BioMed Central Cancer Portal
Biotechniques
Cancer Cell
Cell
Crop Science
Drug Design, Development and Therapy
DDN
Drug Discovery
Dx/PGX
EJHG (European Journal of Human Genetics)
ESHJ
G3 Journal
GEN
Gene Therapy
Genes & Development
Genetics
Genome Research
Genome Web
Genome Web PCR Insider
Genome Web: Clinical Genomics
In Sequence
International Journal of Cancer
Journal of Clinical Microbiology
Journal of Molecular Diagnostics
Lab Matters: Association of Public Health Laboratories
Molecular Cytogenetics
Molecular Microbiology
Nature
Nature Genetics
Nature Heredity
Nature Methods
Nature Reviews Cancer
Nature Reviews Genetics
Nature Reviews Microbiology
PGx Reporter (Genome Web)
Plant Physiology
PLoS Genetics
Proceeding of National Academy of Sciences
Science
Scientific Direct
SeedQuest

Select Science Microbiology
SeqAnswers
The Plant Cell
The Scientist

Interrogatory No. 30:

Identify and describe each instance of confusion, mistake, or deception of any kind between Opposer's ILLUMINA Marks and Applicant's ILLUMIPRO Marks, and identify each person with knowledge of each instance.

Response:

Opposer incorporates its General Allegations as if fully stated herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it is impossible for Opposer to be aware of every instance of consumer confusion as there have most likely been times where consumers were confused but never made Opposer aware of that confusion. Thus, it is impossible to formulate a complete answer for this question.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that it has not yet documented any instances of confusion between Opposer's ILLUMINA Marks and Applicant's ILLUMIPRO Marks by consumers of the parties' good and services.

Respectfully submitted,

ILLUMINA, INC.

Date: **June 10, 2013**

James R. Menker

Attorney for Opposer
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Atlantic Beach, FL 32233

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing "OPPOSER'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO APPLICANT'S FIRST SET OF INTERROGATORIES TO OPPOSER" was served on J. Michael Hurst of Keating Muething & Klekamp PLL, with an address at One East Fourth Street, Suite 1400, Cincinnati, OH 45202, via first class mail, postage prepaid, today **June 10, 2013**.

By: 
James R. Menker

Tel: 904-247-2620
Fax: 202-280-11177
email: eastdocket@holleymenker.com

VERIFICATION

I, William Noon, Ph.D., Patent Attorney of Opposer, am authorized to verify this response on behalf of Opposer. I have read the foregoing OPPOSER'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO APPLICANT'S FIRST SET OF INTERROGATORIES TO OPPOSER and know their contents. The statements are true and correct and are of my own personal knowledge, except for those matters stated to be upon information and belief, and as to those matters, I believe them to be true.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

June 7, 2013
Date

William H. Noon

William Noon, Ph.D.
Patent Attorney
Illumina, Inc.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc., Opposer, v. Meridian Bioscience, Inc., Applicant.	Opposition No. 91194218 (parent) Serial No.: 77/768176 Mark: ILLUMIPRO Opposition No. 91194219 Serial No.: 77/775316 Mark: ILLUMIPRO-10

OPPOSER'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO APPLICANT'S FIRST SET OF INTERROGATORIES TO OPPOSER

Pursuant to Fed. R. Civ. P. 33 and subject to the General Objections and the Objections to Definitions and Instructions in Opposer's Responses and Objections to Applicant's First Set of Interrogatories to Opposer, Illumina, Inc. hereby serves following supplemental responses and objections to Applicant's First Set of Interrogatories to Opposer.

Opposer specifically renews its general objection to Applicant's interrogatories to the extent they seek discovery of confidential, proprietary or sensitive information that is not relevant to the issues in this case and is requested as a means of harassment to Opposer and its business. To the extent any interrogatory seeks documents or information containing confidential or proprietary information or trade secrets, Opposer agrees to provide such information and/or documents, subject to the other objections raised by Opposer, only in accordance with the terms and conditions of the Stipulated Protective Order in this action.

TRADE SECRET/COMMERCIALLY SENSITIVE

Interrogatory No. 4:

Identify all products/services in connection with which the ILLUMINA Marks are used, identifying, in each case, which ILLUMINA Mark is used with which products/services.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the term "used," thus rendering the interrogatory unintelligible.

Subject to and without waiving its objections, Opposer answers that publically available documents from which the answer to this interrogatory may be derived or ascertained can be found on Opposer's publically-accessible websites <<http://www.illuminadx.com/>> and <<http://www.illumina.com>>.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that the ILLUMINA mark is used with all of Opposer's products and services including those set forth in the pleaded registrations and applications including, *inter alia*, chemicals such as reagents for scientific or medical research use for analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing DNA, genotyping, gene expression profiling and high through-put screening; scientific and medical research such as analysis of cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing DNA, genotyping, gene expression profiling and high through-put screening, scientific equipment and instruments such as scanners, hybridization stations and fluidics delivery and computer systems sold as a unit and cassettes containing molecular sensing optical fiber bundles for analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 Dalton, sequencing DNA, genotype, gene expression profiling

and high through-put screening, developing, to the order and specification of others, biological and/or chemical sensing systems which use random array technology to identify organic molecules, compounds and substances, clinical diagnostic reagents, reagent kits, and beads with attached biomolecules, comprised primarily of oligonucleotides and other nucleic acids, natural and modified nucleotides, buffers, labels, and substrates, for clinical diagnostic purposes, Assays and reagents for use in genetic research; diagnostic reagents and preparations, except for medical or veterinary use; diagnostic reagents for scientific or research use; diagnostic reagents for clinical or medical laboratory use; reagent kits comprised primarily of oligonucleotides, enzymes, antibodies, dyes and buffers for nucleic acid detection in the fields of scientific, pharmaceutical and medical research, automated laboratory apparatus and computer systems for use in analysis of biomolecules; nucleic acid sequencers, imaging devices such as electronic imaging apparatus for detecting images and optical signals, and for processing images and optical signals into data, for use in the analysis of biomolecules, and analyzers for use in scientific research; laboratory equipment such as fluid containers, fluid mixers, fluid control valves and temperature-controlled incubators for sample preparation, amplification, mixing, hybridization, incubation, and washing; automated laboratory apparatus and systems such as sample loaders and bar code readers; computer systems such as computer hardware, computer software, and data files for collecting, storing, analyzing and reporting biological information, and for sample tracking and managing projects, laboratory workflow and data, all the foregoing for use in the fields of scientific research; computer software for data collection, management, and analysis of genetic information for use in the field of scientific research; custom synthesis services such as custom synthesis of nucleotides, oligonucleotides, and other nucleic acids, and labeled derivatives thereof and custom nucleotide attachment to substrates, scientific research;

medical research; DNA screening for scientific research purposes; providing reagent sample testing services for others in the fields of science and research related thereto; computer services such as cloud hosting provider services for storing, analyzing and sharing biological information; providing an online network service that enables users to store, analyze and share data in the fields of life science; technical support services such as infrastructure management services for monitoring, administration and management of cloud computing IT and application systems in the fields of life science; consulting services in the field of cloud computing in the fields of life science; providing online non-downloadable software for the custom design and ordering of assays and reagents; design and development of laboratory apparatus and instruments and computer systems for use in analysis of biomolecules; installation and maintenance of computer software and databases used in the field of analysis of biomolecules; consultancy, information and advisory services in the field of analysis of biomolecules; product development services such as developing equipment for use in preparing, detecting, analyzing and sequencing nucleic acids and other biological molecules, and automated laboratory equipment and systems, and computer systems for collecting, storing, analyzing and reporting biological information, and for sample tracking and managing projects, laboratory workflow and data to the order and specification of others, all the foregoing in the fields of scientific and clinical research.

Opposer further answers that the ILLUMINADX mark is used in connection with Opposer's diagnostic products, the ILLUMICODE mark is used with DNA microarrays, and the ILLUMINOTES mark is used with newsletters featuring information in the life sciences field.

Opposer further answers that Opposer's ILLUMINA mark is used on or in connection with all of the products and services offered by Opposer including: (1) sequencing systems; (2) array scanning systems; (3) combined sequencing and array scanning systems; (4) PCR

(polymerase chain reaction) systems; (5) systems for multiplex genetic analysis; (6) DNA sample prep kits; (7) exome enrichment kits; (8) custom enrichment kits; (9) custom amplicon kits; (10) amplicon cancer panels; (11) DNA sample prep kits; (12) targeted resequencing applications; (13) de novo sequencing applications; (14) whole human genome sequencing applications; (15) sequencing automation applications; (16) transcriptome analysis applications; (17) RNA sequencing applications; (18) gene regulation analysis applications; (19) whole-genome genotyping applications; (20) copy number variant analysis applications; (21) custom genotyping programs; (22) formalin-fixed paraffin-embedded analysis applications; (23) focused genotyping applications; (24) single nucleotide polymorphisms discovery and structural variation analysis applications; (25) cytogenetic analysis applications; (26) human and animal linkage analysis applications; (27) gene regulation and epigenetic analysis applications; (28) small RNA sequencing applications; (29) sequencing-based methylation analysis applications; (30) DNA-protein interaction analysis applications; (31) array-based methylation analysis applications; (32) custom methylation analysis applications; (33) gene expression analysis applications; (34) whole-genome gene expression applications; (35) formalin-fixed, paraffin-embedded sample analysis applications; (36) whole-genome DASL HT assay kits; (37) gene expression kits; (38) gene candidate expression kits; (39) splice variant expression kits; (40) protein screening applications; (41) array-based cytogenetics analysis applications; (42) software for analyzing, archiving, and sharing sequencing data; (43) genomic cloud computing services; (44) data analysis software; (45) data analysis software solutions; (46) software for visualizing genomic data; (47) software for positive sample tracking, project and data management, lab workflow management, and reporting; (48) software modules in the field of DNA sequencing; (49) software modules in the field of RNA sequencing; (50) software modules in the field of ChIP

sequencing applications; (51) software modules for genotyping applications; (52) software modules for gene expression applications; (53) software modules for methylation applications; (54) software modules for protein analysis; (55) webinars in the fields of genome sequencing and data analysis; (56) consultation and assistance in the fields of genome sequencing and data analysis; (57) cancer analysis services: (58) providing links to publications and articles in the fields of genome sequencing, rare diseases, bioinformatics and methods and methylation; (59) genetic analysis services; (60) certification of service providers in the field of genetic analysis applications; (61) promoting the microarray and/or sequencing services of others; (62) financing of purchases in the life science field; (63) providing forums for sharing solutions relating to the analysis and management of sequencing and array data; (64) microarray and genome sequencing support services; (65) training programs in the fields of microarrays and genome sequencing; and (66) webinars in the field of genome sequencing.

Opposer further answers that the ILLUMINA mark is used on or in connection with all of the diagnostic-related products and services offered by Illumina including: (1) in vitro diagnostic devices; (2) nucleic acid tests for diagnosing and managing human diseases; (3) nucleic acid tests for diagnosing and managing human infectious diseases and cytogenetics; (4) systems for genotyping, copy number, gene expression, methylation, and protein analysis for molecular diagnostics; (5) systems for genotyping, copy number, gene expression, methylation, and protein analysis for molecular cytogenetics; (6) systems for genotyping, copy number, gene expression, methylation, and protein analysis for cancel biomarker discovery; (7) physician-ordered genome sequencing services; (8) tests and reagents for multiplex analysis of nucleic acid and protein based assays; (9) genetic analysis services; (10) DNA analysis services; (11) microarray and genome sequencing support services; (12) training programs in the fields of microarrays and

genome sequencing; (13) promoting the microarray and/or sequencing services of others; (14) providing links to publications and articles in the fields of genome sequencing, rare diseases, bioinformatics and methods and methylation; and (15) non-invasive prenatal testing.

Opposer further answers that Opposer's ILLUMICODE mark is used on or in connection with DNA microarrays.

Opposer further answers that Opposer's ILLUMINOTES mark is used on or in connection with newsletters featuring information in the life sciences field.

Documents responsive to this interrogatory can be found, *inter alia*, at the following bates numbers: ILLUM-0016 – ILLUM-0064, ILLUM-0166 – ILLUM-0184, ILLUM-0185 – ILLUM-0186, ILLUM-0189 – ILLUM-0190, ILLUM-0191 – ILLUM-0198, ILLUM-0199 – ILLUM-0207, ILLUM-0210 – ILLUM-0217, ILLUM-0218 – ILLUM-0223, ILLUM-0300 – ILLUM-0307, ILLUM-0466 – ILLUM-0473, ILLUM-0474 – ILLUM-0479, ILLUM-0480 – ILLUM-0487, ILLUM-0488 – ILLUM-0522, ILLUM-0523 – ILLUM-0535, ILLUM-0536 – ILLUM-0543, ILLUM-0544 – ILLUM-0586, ILLUM-0587 – ILLUM-0588, ILLUM-0589 – ILLUM-0597, ILLUM-0598 – ILLUM-0614, ILLUM-0615 – ILLUM-0632, ILLUM-0633 – ILLUM-0634, ILLUM-0635 – ILLUM-0656, ILLUM-0657 – ILLUM-0661, ILLUM-0766 – ILLUM-0799, ILLUM-0800 – ILLUM-0803, ILLUM-0804 – ILLUM-0826, ILLUM-0827 – ILLUM-0829, ILLUM-0830 – ILLUM-0835, ILLUM-0836 – ILLUM-0855, ILLUM-0856 – ILLUM-0858, ILLUM-0864 – ILLUM-0880, ILLUM-0881 – ILLUM-0894, ILLUM-0895 – ILLUM-0923, ILLUM-0932 – ILLUM-0935, ILLUM-0953 – ILLUM-0954, ILLUM-0955 – ILLUM-0958, ILLUM-0959 – ILLUM-0960, ILLUM-0961 – ILLUM-0968, ILLUM-0969 – ILLUM-0972, ILLUM-0973 – ILLUM-0980, ILLUM-1007 – ILLUM-1008, ILLUM-1009 –

ILLUM-1066, ILLUM-1083 – ILLUM-1092, ILLUM-1093 – ILLUM-1110, ILLUM-1113 – ILLUM-1145, ILLUM-1154 – ILLUM-1160.

Interrogatory No. 5:

Identify and describe which products/services included in the response to Interrogatory No. 4 are intended for use/actually used in the Clinical Diagnostics area.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "intended for use" and "actually used" thus rendering the interrogatory unintelligible.

Subject to and without waiving its objections, Opposer answers that many of its products are used in connection with Clinical Diagnostics. However, since Opposer does not know how each of its products is actually used by third parties, it cannot provide a definitive list. Subject to and without waiving its objections, Opposer further answers that its publically-accessible website, <<http://www.illuminadx.com/>>, identifies Opposer's products and services that are intended for use in the Clinical Diagnostics.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that its (i) BeadXpress System and related VeraCode kits and (ii) MiseqDx Instrument for next-generation sequencing and related kits are cleared for use in clinical diagnostics, are intended for use in the Clinical Diagnostics area and are actually used in the Clinical Diagnostics area.

Opposer further answers that the products/services included in the response to Interrogatory No. 4 that are intended for use/actually used in the clinical diagnostics area include: (1) in vitro diagnostic devices; (2) nucleic acid tests for diagnosing and managing

human diseases; (3) nucleic acid tests for diagnosing and managing human infectious diseases and cytogenetics; (4) systems for genotyping, copy number, gene expression, methylation, and protein analysis for molecular diagnostics; (5) systems for genotyping, copy number, gene expression, methylation, and protein analysis for molecular cytogenetics; (6) systems for genotyping, copy number, gene expression, methylation, and protein analysis for cancel biomarker discovery; (7) physician-ordered genome sequencing services; (8) tests and reagents for multiplex analysis of nucleic acid and protein based assays; (9) genetic analysis services; (10) DNA analysis services; (11) microarray and genome sequencing support services; (12) training programs in the fields of microarrays and genome sequencing; and (13) non-invasive prenatal testing.

Documents responsive to this interrogatory can be found, *inter alia*, at the following bates numbers: ILLUM-0016 – ILLUM-0064, ILLUM-0166 – ILLUM-0184, ILLUM-0185 – ILLUM-0186, ILLUM-0199 – ILLUM-0207, ILLUM-0210 – ILLUM-0217, ILLUM-0218 – ILLUM-0223, ILLUM-0300 – ILLUM-0307, ILLUM-0466 – ILLUM-0473, ILLUM-0474 – ILLUM-0479, ILLUM-0488 – ILLUM-0522, ILLUM-0536 – ILLUM-0543, ILLUM-0544 – ILLUM-0586, ILLUM-0598 – ILLUM-0614, ILLUM-0615 – ILLUM-0632, ILLUM-0633 – ILLUM-0634, ILLUM-0635 – ILLUM-0656, ILLUM-0657 – ILLUM-0661, ILLUM-0766 – ILLUM-0799, ILLUM-0804 – ILLUM-0826, ILLUM-0827 – ILLUM-0829, ILLUM-0932 – ILLUM-0935, ILLUM-0953 – ILLUM-0954, ILLUM-0955 – ILLUM-0958, ILLUM-0969 – ILLUM-0972, ILLUM-0973 – ILLUM-0980, ILLUM-1007 – ILLUM-1008, ILLUM-1083 – ILLUM-1092, ILLUM-1113 – ILLUM-1145, ILLUM-1154 – ILLUM-1160.

Interrogatory No. 13:

Identify Opposer's top 25 customers that have purchased from Opposer and/or its distributors products or services bearing the ILLUMINA Marks in the United States in the last 5 years.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "top," "customers" and "field" in that it fails to provide clear criteria sufficient for Opposer to compile a list of its "top 25 customers," thereby rendering the interrogatory unintelligible.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that Opposer's top 25 customers that have purchased from Opposer and/or its distributors products or services bearing the ILLUMINA Marks in the United States from 2009 to 2013 are listed in document bates number: ILLUM-1558 (marked as Trade Secret/Commercially Sensitive).

Interrogatory No. 14:

Identify Opposer's top 25 customers that have purchased from Opposer and/or its distributors products or services bearing the ILLUMINA Marks in the Clinical Diagnostics field in the United States in the last 5 years.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "top," "customers" and "field" in that it fails to provide clear criteria sufficient for Opposer to compile a list of its "top 25 customers," thereby rendering the interrogatory unintelligible.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that it does not maintain its business records in a manner that would reasonably permit it to determine which of its customers have purchased its products or services bearing the ILLUMINA Marks specifically for use in the Clinical Diagnostics field and, therefore, cannot provide a ranking of such customers.

Opposer further answers that its customers in the Clinical Diagnostics field include the Broad Institute, John Hopkins University, Sequenom, Washington University, Baylor College of Medicine, University of Washington, Yale University, Mayo Foundation for Medical Education and Research, and Stanford University.

Interrogatory No. 15:

Identify by title and job function the individuals working at each customer identified in the response to Interrogatory Nos. 13 and 14 who are responsible for ordering products/services bearing the ILLUMINA Marks.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "working," "customer," and "responsible," thus rendering the interrogatory unintelligible.

Subject to and without waiving its objections, Opposer responds that it is not in possession of the requested information about the employees of third parties but that such information may be publically available.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that the individuals that Opposer believes are responsible for ordering products/services bearing the ILLUMINA Marks

from Opposer are identified in the charts identified in the documents produced in response to Interrogatory No. 13.

Opposer further answers that the customers identified in response to Interrogatory No. 14 are also in the charts identified in the documents produced in response to Interrogatory No. 13.

Interrogatory No. 21:

Identify the date on which Opposer first entered the Clinical Diagnostics market with products/services bearing the ILLUMINA Marks.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "first entered" and "market" thus rendering the interrogatory unintelligible.

Subject to and without waiving its objections, Opposer entered the Clinical Diagnostics market in 2006.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer entered the Clinical Diagnostics market with products/services bearing the ILLUMINA Marks at least by 2006. See also Opposer's responses to Interrogatories 44 and 45.

Interrogatory No. 22:

Identify all products/services offered by Opposer or its distributors that use any of the ILLUMINA Marks as the primary brand for the product as opposed to those that use the ILLUMINA Marks as a house mark.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "offered," "use," and "primary brand" thus rendering the interrogatory unintelligible.

Subject to and without waiving its objections, Opposer answers that publically available documents from which the answer to this interrogatory may be derived or ascertained can be found on Opposer's publically-accessible websites <<http://www.illuminadx.com/>> and <<http://www.illumina.com>>.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that while some of its products are branded with a mark other than the ILLUMINA Marks, the ILLUMINA marks are used on all products sold by Opposer and is used in connection with all services rendered by Opposer.

Interrogatory No. 32:

Identify Opposer's top ten (10) competitors in the molecular diagnostics market.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "top, "competitor," and "molecular diagnostics market," thus rendering the interrogatory unintelligible.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that it considers the following entities to be its top ten (10) competitors in the molecular diagnostics market.

Qiagen
Roche

Abbott
Thermo Fischer (including Life Technologies)
Immucor
Luminex
Hologic
Dako
Fujirebio Diagnostics
bioMerieux

Interrogatory No. 37:

Identify the specific diseases and/or disease states for which Opposer has developed Clinical Diagnostics tests that use the ILLUMINA Marks.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the term "developed" thus rendering the interrogatory unintelligible. Subject to and without waiving its objections, Opposer answers that publically-available documents from which the answer to this interrogatory may be derived or ascertained can be found on Opposer's publically-accessible websites <<http://www.illuminadx.com>> and <<http://www.illumina.com>>. Subject to and without waiving its objections, Opposer answers that representative examples of Clinical Diagnostics tests capable of being performed by Opposer's products include genetic defects, blood clotting, and irregularities in metabolizing drugs.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that it has obtained FDA approval for the (i) MiSeqDx Cystic Fibrosis 139-Variant Assay; (ii) MiSeqDX Cystic Fibrosis Clinical Sequencing Assay; (iii) MiSeqDx Univeral Kit; and (iv) Illumina VeraCode Genotyping Test for FactorV and Factor II. Opposer plans to obtain FDA approval for (i) non-invasve prenatal fetal aneuploidy screening on its HiSeq 2500 instrument and (ii) an oncology

companion diagnostic test on its MiSeqDx instrument. Opposer further answers that Illumina has developed clinical sequencing services that are provided in its CLIA-certified Clinical Service Laboratory, including: (i) TruGenome Undiagnosed Disease Test; (ii) TruGenome Predisposition Screen; and (iii) TruGenome Technical Sequence Data. Opposer further answers that it has developed and is currently developing several other clinical diagnostic tests that use the ILLUMINA Marks for various cancer biomarkers and inherited diseases.

Interrogatory No. 38:

Explain what Opposer's "DNA microarray" is, how it is used, who uses it, and whether/how it is used for Clinical Diagnostics purposes.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "used," "uses," and "purposes" thus rendering the interrogatory unintelligible. Opposer further objects to this interrogatory to the extent that it seeks information and identification of documents that are publicly available and therefore publicly accessible to the Registrant. Moreover, this interrogatory cannot be answered succinctly. Subject to and without waiving its objections, Opposer answers that publically available documents from which the answer to this interrogatory may be derived or ascertained can be found on Opposer's publically-accessible website <<http://www.illumina.com/ >>. Subject to and without waiving its objections, Opposer further answers that a "DNA microarray" can be used in Clinical Diagnostics.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that a DNA microarray is a large collection of short DNA sequences that are arranged on a solid surface, such as a silicon

chip or a microscopic glass bead. Opposer further answers that Opposer's microarrays can have millions of individual DNA sequences that can correspond to genetic sequences in humans and other species. Opposer's customers can use microarrays to test for the presence or absence of specific genetic sequences, such as disease-causing mutations, in biological samples. These customers include researchers, clinicians, physicians, pharmaceutical companies, academia, clinical laboratories, hospitals, hospital administrators, purchasing agents, clinical investigators/principal investigators, government agencies, agricultural companies, forensic/criminal agencies, biotechnology companies, consumer genomics companies, and tissue banks. At present, the BeadXpress system, which received a separate 510(k) market clearance, is FDA-cleared for in vitro diagnostic use with the VeraCode Genotyping Test for Factor V and Factor II.

Interrogatory No. 39:

Explain what Opposer's "DNA sequencing" is, how it is used, who uses it, and whether/how it is used for Clinical Diagnostic purposes.

Response:

Opposer incorporates its General Objections as if fully set forth herein. Opposer objects to this interrogatory as overly broad, unduly burdensome and vague in that it fails to define the terms "used," "uses," and "purposes" thus rendering the interrogatory unintelligible. Opposer further objects to this interrogatory to the extent that it seeks information and identification of documents that are publicly available and therefore publicly accessible to the Registrant. Moreover, this interrogatory cannot be answered succinctly. Subject to and without waiving its objections, Opposer answers that publically available documents from which the answer to this interrogatory may be derived or ascertained can be found on Opposer's publically-accessible

website <<http://www.illumina.com/ >>. Subject to and without waiving its objections, Opposer further answers that "DNA sequencing" is used in Clinical Diagnostics.

Supplemental Response and Objection(s):

Subject to and without waiving its objections, Opposer answers that DNA sequencing is the process of determining the sequence of nucleotides in a sample of deoxyribonucleic acid (DNA). Opposer further answers that its customers can perform DNA sequencing to obtain genetic information about an individual (e.g. the complete sequence of all chromosomes) or for specific sequences of interest (e.g. disease-related mutations). These customers include researchers, clinicians, physicians, patients, pharmaceutical companies, academia, clinical laboratories, genetic counselors, information technologists, bioinformaticists, hospitals, hospital administrators, purchasing agents, clinical investigators/principal investigators, government agencies, agricultural companies, forensic/criminal agencies, biotechnology companies, consumer genomics companies, and tissue banks. At present, the MiSeqDX instrument, which received a separate 510(k) market clearance, is FDA-cleared for in vitro diagnostic use with the MiSeqDx Cystic Fibrosis 139-Variant Assay, MiSeqDx Cystic Fibrosis Clinical Sequencing Assay, and MiSeqDX Universal Kit. Illumina also offers clinical sequencing services that are provided in its CLIA-certified Clinical Service Laboratory, including: (i) TruGenome Undiagnosed Disease Test; (ii) TruGenome Predisposition Screen; and (iii) TruGenome Technical Sequence Data.

Respectfully submitted,

ILLUMINA, INC.

Date: **February 3, 2014**

James R. Menker

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VERIFICATION

I, William Noon, Ph.D., Patent Attorney employed by Opposer, am authorized to verify this response on behalf of Opposer. I have read the foregoing OPPOSER'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO APPLICANT'S FIRST SET OF INTERROGATORIES TO OPPOSER and know their contents. The statements are true and correct and are of my own personal knowledge, except for those matters stated to be upon information and belief, and as to those matters, I believe them to be true.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

1/4/14
Date

William Noon, Ph.D.
Patent Attorney
Illumina, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing "OPPOSER'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO APPLICANT'S FIRST SET OF INTERROGATORIES TO OPPOSER" was served on J. Michael Hurst of Keating Muething & Klekamp PLL, with an address at One East Fourth Street, Suite 1400, Cincinnati, OH 45202, via first class mail, postage prepaid, today **February 4, 2014**.

By: 
Laura K. Greer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

ILLUMINA, INC.,	)	
	)	
OPPOSER,	)	
	)	
vs.	)	OPPOSITION NO:
	)	91211615
MERIDIAN BIOSCIENCE, INC.,	)	
	)	
APPLICANT.	)	
	)	

Deposition of NAOMI O'GRADY, taken on behalf of the Applicant, Meridian Bioscience, Inc., at 12790 El Camino Real, San Diego, California, commencing at 7:48 a.m., on Thursday, December 4, 2014, before Tracy M. Fox, CSR Number 10449, Certified Shorthand Reporter in and for the State of California

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EXHIBITS

EXHIBITS (Continued)

SAN DIEGO, CALIFORNIA, THURSDAY
DECEMBER 4, 2014
7:48 A.M.

NAOMI O'GRADY,
called as a witness and sworn in by
the deposition officer, was examined
and testified as follows:

DEPOSITION OFFICER: Would you raise your right hand.

Do you solemnly state that the testimony you are about to give in the following deposition will be the truth, the whole truth, and nothing but the truth?

THE WITNESS: Yes.

DEPOSITION OFFICER: Thank you.

EXAMINATION

BY MR. HANKINSON:

Q. Good morning.

A. Good morning.

Q. We were just introduced, but I'll say it again.

I'm Tom Hankinson. I represent Meridian in this case.

With me today is Mike Hurst, who also represents Meridian.

Thank you for coming in.

Have you ever been deposed before?

A. No.

Q. I'll be asking questions. You'll be giving the answers. We'll try not to talk over each other so that the court reporter here can take down the complete question and answer.

Is that okay?

A. Yes.

Q. If at any point you don't understand my question or would like for it to be repeated, please just ask.

Is that okay?

A. Yes.

Q. If you answer, I'll assume that you understood it and heard it.

Is that fair?

A. Yes.

Q. These are just preliminaries.

If at any point you'd like to take a break, just let us know. Okay?

A. Yes.

Q. You'll have to answer any question that's already pending, and then we can take the break.

Do you understand?

A. Yes.

Q. And you're doing a great job already, but try to answer with a "Yes" or a "No" instead of a head nod or an "Uh-huh," because that can be ambiguous in the transcript.

Is that fair?

A. Yes.

Q. Thank you.

I'd like to start by talking about your background a little bit.

Would you please take me through your education after high school.

A. I received a bachelor's degree in biology

with a specialty in cell and molecular biochemistry at San Diego State University.

I also have a master's degree in business with an emphasis in entrepreneurship, also from San Diego State University.

Q. Is that your complete formal education after high school?

A. I also have a certificate in design control from the University of California San Diego.

Q. The bachelor's in biology, was that a four-year program?

A. Yes.

Q. Your MBA, was that two years? Three years?

A. I'm not sure what the formal duration was.

Q. Were you working at the time?

A. Yes.

Q. Where were you working then?

A. I was working at a biotech company called Nanogen, and also at Illumina at the time I was getting that degree.

Q. No wonder it's a blur.

And then how long was the program at the University of California San Diego in design control?

A. It was a several-week program.

Q. About when did you go through that design-control program?

A. It was during my time at Nanogen.

DEPOSITION OFFICER: Can you spell that?

THE WITNESS: N-a-n-o-g-e-n.

DEPOSITION OFFICER: Thank you.

THE WITNESS: Prior to 2007.

///

BY MR. HANKINSON:

Q. Do you use your biology background and your specialty in cell and molecular biochemistry in your work at Illumina?

A. Yes.

Q. And in what ways would you say that that background applies to your current work at Illumina?

A. The field of molecular diagnostics is looking at DNA and RNA sequences, so the specialty

in cell and molecular biochemistry is very useful to that understanding.

Q. Your current work deals with -- is it marketing of oncology services?

A. Product marketing for oncology. My focus is the molecular diagnostics market.

Q. And your understanding or definition of "molecular diagnostics" -- just to make sure that I got it right -- is it that that field deals with looking at DNA and RNA sequences?

A. No, not necessarily.

There are other applications of molecular diagnostics beyond just looking at sequences.

Q. So I'm sorry if I misunderstood you.

You were answering that you use your biology background in your work at Illumina insofar as that work deals with looking at DNA and RNA sequences in the products and services that are offered?

A. The -- I'm sorry?

Is there a question -- was that a question?

Q. Did I have that right?

A. There are additional uses of -- there are additional fields of molecular diagnostics beyond DNA and RNA that I focused on in my time at Illumina.

Q. Okay. And would you please give me an exhaustive list of those?

A. We --

Q. And do you understand "exhaustive" meaning all of them?

A. Yes.

Q. Not that it's going to make us tired, although it might.

A. Yeah.

Q. Sorry for interrupting.

A. We have a -- a technology called the BeadXpress on which there -- we offered beads that were carboxylated that enable protein and cytokine --

Q. That's c-y-t-o- --

A. C-y-t-o-k-i-n-e.

-- assays.

So, in addition, we also detect methylation.

Q. That's m-e-t-h-y-l-a-t-i-o-n; right?

A. Yeah.

Q. Oh, is that complete?

A. I'm thinking.

Yes, that's complete.

Q. And would you please tell me any other aspects of molecular diagnostics that are not looking at DNA and RNA sequences that Illumina engages in its products and services?

Because I was asking about your work, and now I'm broadening it out to the company.

MR. HORNE: You mean ever or now or --

BY MR. HANKINSON:

Q. I'd like to hear both, so let's start with at the current time.

A. The carboxylated beads that I described are enabling of protein detection, which has application in molecular diagnostics.

Q. And how is that different from the one that you listed for your own work?

A. It's the same.
Q. Okay. Are there any in addition to what we've discussed already?
A. Not that I'm aware of.
Q. And in your work currently in oncology, but previously more generally, would you expect to be aware of the products and services offered by Illumina?
A. I can't say that I would be aware of all products and services offered by Illumina.
Q. What about within the field of molecular diagnostics?
A. It's possible that there were others that I was not aware of.
Q. Setting aside sort of a weird situation in which -- like just in the realm of possibility anything can happen, do you have any reason to believe that you're unaware of a molecular diagnostics product or service that Illumina currently markets or sells?
A. Not markets or sells.
Q. You might not be aware of R&D that's going

on but isn't yet to market; is that what you're saying?
A. Yes.
Q. And now let's ask the same question for the past.
So any discontinued or no longer sold or marketed products or services of Illumina within the field of molecular diagnostics, would you please list any of those that you're aware of.
A. The BeadXpress Factor V and II IVD is discontinued.
Q. So that's "Factor," Roman Numeral "V," and "Factor," Roman Numeral "II, IVD"?
Do I have that right?
A. It's probably not the official name of the product, but in -- in general that's what it was detecting.
Q. What was the product?
A. Are you asking me for the name?
Q. Yes.
A. I -- I'm not sure of the exact brand name.

Q. The BeadXpress Reader was the machine that was used in providing that?
A. Yes.
Q. Was the factor -- well, could you just explain a little bit more about how that Factor V and Factor II detection worked?
What was Illumina offering?
A. Sure.
It was a DNA genotyping assay for variants associated with Factor V and II Leiden that was detected on the BeadXpress Reader.
Q. Is your answer complete?
A. Are you -- are you looking for more --
Q. No, I just want to make --
A. -- specific molecular --
Q. I just -- before I ask my next question, I didn't know if you were done speaking or not.
A. I'm done speaking.
Q. Could you spell "Leiden"?
A. L-e-i-d-e-n.
Q. And "variants" is v-a-r-i-a-n-t-s?
A. Yes.

Q. "Genotyping," G-e-n-o-t-y-p-i-n-g?
A. Yes.
Q. That has to do with genetics, I'm assuming?
A. It's inherited, yes.
Q. So genotyping is a field related to inherited genes?
A. Yes.
Q. Who was using the BeadXpress machine when it was used in detecting Factor V or Factor II at the time that that service was offered?
A. Molecular Diagnostics Laboratories.
Q. The laboratory would purchase a BeadXpress Reader?
Do I have that right?
A. Yes.
Q. Was that the first IVD product that Illumina -- let me ask that a different way.
Was that the first use of an Illumina product in the field of IVD?
MR. HORNE: Vague.
THE WITNESS: The -- no.

BY MR. HANKINSON:
Q. How many came before that?
A. Many. There were many products registered with the FDA as a Class I exempt device prior to Factor V and II.
Q. We were listing the products or services sold or marketed by Illumina in the past that are not currently offered in the field of molecular diagnostics, and we just discussed the BeadXpress Reader --
A. Uh-huh.
Q. -- as it pertains to Factor V and II and IVD.
A. Uh-huh.
Q. Are there any others?
A. Yes.
Q. Could you go on?
A. The -- I'm unclear on exactly which products are discontinued versus still available.
Q. How about all the ones we haven't talked about already.
A. Whether or not they're discontinued?

Q. Yes. I think if you knew about them, you would have -- and they were not discontinued, you would have already listed them.
If you remember more, add to that answer.
Does that make sense?
A. I think -- I think -- no, it doesn't make sense.
I'm sorry.
Q. Okay.
A. Previously I was describing fields of use of the technology, and I didn't list exhaustively all of Illumina's products.
And now you're asking me to list specific products. I -- I understand that you're asking me to list specific products, and -- and that's why I'm confused.
Q. So when we were discussing Illumina's current products and services that are offered and marketed or sold in the field of molecular diagnostics --
A. Uh-huh.
Q. -- you were listing fields as opposed to

products?
A. Yes.
Q. And in each field that you listed, there might be additional, like, product names?
A. Yes.
Q. But the fields that you discussed were for the current marketing and sales of Illumina -- the BeadXpress when used with carboxylated --
Did we spell that for you?
DEPOSITION OFFICER: Yes.
THE WITNESS: Okay.
BY MR. HANKINSON:
Q. -- beads and detecting methylation.
Are those all fields?
A. The fields of -- the -- the analytes that can be detected with Illumina technology are DNA, RNA, and protein.
There are methods of detection available from Illumina with multiple instruments and products in those areas.
DEPOSITION OFFICER: How do you spell "analytes"?

THE WITNESS: A-n-a-l-y-t-e-s.
BY MR. HANKINSON:
Q. Pardon me for being simplistic.
There are machines that are sold --
A. Yes.
Q. -- to laboratories; right?
A. Yes.
Q. And I kind of view those as like platforms to run certain things at the lab?
A. Yes.
Q. And then there's inputs to that process that are also sold by Illumina?
A. That's right.
Q. Including beads?
A. Yes.
Q. And including oligo? What's that? Are those in the beads?
What starts with oligo, o-l-i-g-o?
A. What starts with oligo?
Q. I'm blanking.
A. I don't understand your question.
I'm sorry.

Q. I'm trying to remember some of the inputs to those platforms that are sold by Illumina.
I'm remembering like --
A. Sure.
Q. -- a word that starts with that.
A. That -- it's -- it's not -- it's not that simple.
Q. Okay.
A. It's -- it's just not that simple.
There -- there are many different assay methods that Illumina offers and consumables associated with them that interface with our array and sequencing platforms.
Q. When you say "array and sequencing platforms," are those machines that are sold to laboratories?
A. Yes.
Q. And one of those is the BeadXpress; right?
A. Yes.
Q. Is there a BeadArray machine?
A. A BeadArray Reader.

Q. And what are the other ones, currently?
A. Genome analyzer, MiSeq and MiSeqDx, NextSeq, HiSeq.
And there are various versions of the HiSeq available.
Q. What was the cheapest one of those?
A. I'm sorry.
There's one more instrument that I can't recall the name of that was a PCR machine. That was the cheapest.
Q. How much did that cost?
A. I don't recall the exact price.
Q. It's discontinued now?
A. It's discontinued.
Q. Was it more than 10,000 dollars?
A. Yes.
Q. Can you give me a ballpark so I don't just march up by tens?
A. I think it was in the realm of 30- to 50,000.
I don't remember the exact price, but it was a low-priced instrument for PCR.

Q. And that's no longer offered?
A. That's not available anymore.
Q. What's the price range for a genome analyzer?
A. I'm not sure. I -- I don't want to speculate on that one. I -- I don't know the prices.
I -- I do know them of the other instruments.
Q. It is more than 30- to 50,000 dollars?
A. Yes.
Q. What about the MiSeq.
And that's M-y --
A. No. M-i.
Q. M-i?
A. S-e-q.
Q. With a capital "S"?
A. Yes.
Q. How much will that run me?
A. 98,000.
Q. And what about the MiSeqDx?
A. 125,000.

Q. NextSeq?
All of these "Seqs" are capital S-e-q.
DEPOSITION OFFICER: Thanks.
THE WITNESS: 250,000.
BY MR. HANKINSON:
Q. I'm almost afraid to ask about HiSeq.
A. Because there are so many versions, I'm not certain.
Q. What's the cheapest HiSeq?
A. I'm not sure.
Q. Is it more than 250,000?
A. Yes.
Q. Is it less than a million?
A. Yes.
Q. Does it run the gamut between those two numbers?
A. Yes.
MR. HANKINSON: Gamut is g-a-m-u-t.
Do people use that anymore?
DEPOSITION OFFICER: It's right here, believe it or not (indicating). Yes, my dad uses gamut all the time.

MR. HANKINSON: That's funny.
BY MR. HANKINSON:
Q. What's the difference between the MiSeq and the MiSeqDx?
A. FDA approval. We have FDA approval on the MiSeqDx.
Q. Otherwise it's the same?
A. Not completely.
Q. So what are the differences?
A. There's a version of chemistry that is currently not supported on the MiSeqDx.
Q. Why not?
A. Because it came after FDA approval.
I'm sorry. That's not correct.
It came during development of the MiSeqDx for clearance.
Q. "Clearance," is that another term for FDA approval?
A. It's a different type of FDA submission.
Q. Is it when there's an FDA-approved product and then it's cleared for another use or -- just --
A. No.

Q. -- correct me. I'm just --
A. Yes.
Q. -- trying to stab around and get at it.
A. A 510(k) submission, which is a type of application to the FDA, is cleared; and a PMA is approved.
It has to do with risk and safety and effectiveness.
Q. Are all of Illumina's products cleared, or are some of them approved in the field of diagnostics?
A. We have some instruments that are cleared; we have not yet submitted a PMA to the FDA.
Q. So the MiSeq platform existed prior to some point in time when it was decided to try to clear that, or something similar, through the FDA; right?
A. No.
Q. Okay. Correct me.
A. When that instrument was conceived, our intention was to solis- -- to go to the clinic with the system and seek FDA clearance or approval with

multiple applications.
Q. And when was that?
A. Are you asking me when development initiated?
Q. Yes.
A. I don't know.
Q. What's the first date on which you remember learning of the MiSeq?
A. I -- I don't recall.
Q. What is a Class I exempt device?
A. It's a -- I am not an expert in regulatory, but I can explain what it means to me.
Q. Please do so.
A. It's a low-risk device that the FDA grants exemption to a certain ranking.
Q. Is your field right now marketing?
A. I am a product marketer, and I also have responsibility for some development projects.
Q. Do you use your biology background with your specialty in selling molecular biochemistry in your role as a product marketer, or only in your role as taking part in certain development

projects?
A. Both.
Q. In what ways does that apply to your role as a product marketer?
A. Communicating to customers, developing marketing literature, planning life cycle of products.
Q. So this is a different kind of marketing than I'm used to where somebody's in communications and -- and they're kind of working with advertisement agencies or coming up with like a -- how much they're going to spend and how they're going to do it.
I mean, those people aren't really scientifically trained to talk to the customers, I guess, because the products are not always so sophisticated?
MR. HORNE: I just that lacks foundation.
Is that a question?
THE WITNESS: Are you asking me a question?
BY MR. HANKINSON:

Q. Yeah.
I mean, does that strike you as right?
MR. HORNE: Vague, lacks foundation.
THE WITNESS: I -- I don't -- I don't understand.
BY MR. HANKINSON:
Q. I'm sorry. That's because it's vague and it lacks foundation.
So when you are communicating to customers, how are you applying your biology background with your specialty in cell and molecular biochemistry?
A. Customers in the field of molecular diagnostics are testing for -- they're looking for answers to questions that are answered by molecular biology, so my education gives me credibility in communicating with that customer.
Q. So they expect somebody who's marketing the product to like know the science?
MR. HORNE: Lacks foundation.
THE WITNESS: I don't know what the customer -- if -- if all customers expect that.

BY MR. HANKINSON:
Q. But you find that that gives you credibility with them?
A. I -- I -- yes.
Q. So they all must be scientifically trained, and they're in that field; right?
MR. HORNE: Lacks foundation, vague.
BY MR. HANKINSON:
Q. Is it true?
MR. HORNE: Compound.
THE WITNESS: You know, I don't understand your question.
I'm sorry.
BY MR. HANKINSON:
Q. Yeah. I mean, so you're credible to them because you have this background and can speak the language.
Is that fair to say?
A. Our -- our customers are lab directors in a molecular laboratory and ask questions about technology.
Q. What kind of questions about the

technology do they ask?
A. How it can answer their molecular -- or their clinical question.
Q. What other types of questions?
A. Does a person have disease? Will they respond to a drug?
Q. I'm asking you what other types of questions do the lab directors that you're talking about ask about the product?
A. What's the throughput in terms of samples per run?
What's the laboratory workflow?
How is reporting done?
They ask questions about how it will be implemented into their laboratory.
Q. Now, Illumina offers training in those aspects; right?
MR. HORNE: Vague.
THE WITNESS: Can you ask the question in another way?
BY MR. HANKINSON:
Q. Illumina offers training in how an

Illumina platform will be implemented in a lab; right?
MR. HORNE: Vague.
THE WITNESS: Can you ask it another way?
BY MR. HANKINSON:
Q. Does Illumina offer training?
A. Yes.
MR. HORNE: Vague.
I'm just saying I'm not -- I'm objecting -- I don't know if you mean to the customers or the employees.
That's why I'm objecting, so...
BY MR. HANKINSON:
Q. Does Illumina offer training to personnel at laboratories that buys platforms?
A. Yes.
Q. Does part of the training of the personnel at the laboratories that buy Illumina's platform include implementation of the platform at their laboratory?
A. Yes.
Q. Nevertheless, the lab directors who are

making the purchasing decisions ask you questions prior to purchasing as well; is that correct?
A. Yes.
Q. And those questions are as detailed as how the work flow in their laboratory will work when they are implementing Illumina's platform; is that right?
A. Are you -- are you asking me if that's the --
Q. It gets down to that level of detail?
A. Yes.
Q. And when we talk about laboratory work flow, it has to do with who at the lab will have to, you know, prepare whatever's going to be the input to the platform, how long that will take them, who else might be involved, how long it will be in the platform while it's performing whatever it does, how people will be notified that it's done, who's going to take it out, how long that's going to take them, what kind of data is coming out of it, and how long that takes.
These are the types of questions that

they're asking?
MR. HORNE: Compound.
THE WITNESS: You -- you did say a lot of things there kind of quickly.
Can -- can you maybe ask me a different question in a different way?
BY MR. HANKINSON:
Q. Sure.
We've established that the lab directors, prior to purchasing Illumina's platforms, ask about laboratory workflow?
A. Yes.
Q. And I'm trying to give examples of what laboratory workflow is.
A. Sure.
Q. Would you want to provide them instead of me stabbing at them?
A. Sure.
Well, usually a lab manager will be thinking from sample to answer. So how -- how is that workflow going to impact their laboratory space and resources from sample to answer.

And then they ask questions in that regard.
Q. Does "resources" include people?
A. Yes.
Q. And what else does resources include?
A. Equipment, consumables.
Q. Does Illumina sell consumables that are used by its customers outside of their use with Illumina's platforms?
A. I don't understand your question.
Q. Does Illumina sell any consumables that are used for purposes in the customers' laboratories other than their use with platforms that have been sold by Illumina?
A. Yes.
Q. Could you tell me what those consumables are and how they are used outside of platforms that are sold by Illumina?
A. Illumina has a company we acquired called Epicentre that provides consumables, like enzymes, that are useful with Illumina platforms and for other purposes.

Q. Is that it?
A. I'm -- I'm not able to provide an exhaustive list of consumables that could be used outside of our instruments.
Q. So prior to purchasing an Illumina platform, the lab director is interested in the space within the lab and the utilization of the lab's resources.
We already discussed that; right?
A. Yes.
Q. And when we say that a resource includes people, what are the people doing with the platform that's, you know, taking up lab resources?
A. Executing the assay process.
Q. And the idea -- and being curious about this if I'm a lab director -- is that the people who are executing that process would have other things to do.
You want to sort of get a sense of how long it takes and when these things are going to be occurring?
Do I have that right?

A. Yes.
Q. And then in terms of consumables, if I'm a lab director who's considering purchasing a platform from Illumina, I want to know in advance, "Well, what are the consumables that I'm then going to have to continue to purchase in the future in order to get the value out of platform?"
Right?
A. I -- can you ask the question another way?
Q. The lab director is interested in questions about the consumables as a, you know, lab resource that's going to be used; right?
A. They're interested -- I'm -- I'm sorry. I don't understand the question.
Q. So you said that lab directors ask questions about how the platform's going to impact the space and resources?
A. Yes.
Q. And you listed consumables as one of resources?
A. Yes.
Q. And I'm trying to get at details about

that.
A. Uh-huh.
Q. And so when they're asking questions about consumables --
A. Uh-huh.
Q. -- they're trying to plan for the future; right?
A. Maybe.
Q. Okay. And when they're -- what else would they be planning for?
MR. HORNE: Pardon me. Lacks foundation.
THE WITNESS: I don't -- I'm -- I'm not -- I don't understand your question. I'm sorry.
BY MR. HANKINSON:
Q. Well, they're asking a question before they purchase a very expensive machine; right?
A. I do not agree that our instruments are very expensive.
Q. They're asking a question about consumables before they purchase a machine that costs between 50,000 dollars and a million dollars;

right?
A. I don't agree that the -- a customer would have decided what instrument they want before they are having a question about consumables and what the price of the instrument is.
Q. You're marketing the platform. That's how we started talking about this; right?
A. Yeah. Yes.
Q. And so when you say they would have already chosen the platform before they're asking these questions of a marketing person, I don't understand your answer.
A. Our systems and consumables are capable of answering many types of questions.
So the right combination of instrument and consumables would be discussed with a marketing or sales representative as part of that conversation.
Q. Are there marketing or sales representatives assigned to particular labs and lab directors?
A. Yes.
Q. So each lab has its own account manager,

in a sense?
What is the term?
A. I'm not certain of the exact term that we use.
And it's not -- some -- some labs may have more than one account manager.
Q. Do --
A. So --
Q. -- the labs know who the account manager is?
A. Labs where we are selling products know who their account manager is.
Q. And that's the person who governs the relationship on behalf of Illumina with that lab going forward; right?
A. I don't know what you mean by "governs."
Q. Is the main contact person for the lab?
A. The account manager is the main contact person for the lab for sales.
Q. About how many labs are in the market?
A. What type of lab?
Q. About how many labs that are permitted to

perform diagnostic work are in the market?
MR. HORNE: Vague.
THE WITNESS: Can you describe what you mean by "market"?
BY MR. HANKINSON:
Q. The pool of labs to which Illumina can sell its products in the field of molecular diagnostics.
A. In -- my -- my -- globally? Are you asking globally?
I don't know the exact number globally.
Q. What about in the United States?
A. In -- in the United States there is a type of a customer called a CLIA laboratory that is permitted to run diagnostic tests, and I don't know the exact number of these labs.
Q. The FDA is the body that's permitting them to do so?
A. No.
Q. Who is permitting them to do so?
A. The -- the permission or the -- the governing -- ah.

Laboratories are permitted to run tests under the CLIA laboratory improvement amendments. They're regulated by C.A.P. and CLIA.
C.A.P. is the College of American Pathology.
Q. What is involved --
DEPOSITION OFFICER: Can you spell CLIA? Sorry.
THE WITNESS: C-L-I-A. It's capital C-L-I-A.
DEPOSITION OFFICER: Thank you.
BY MR. HANKINSON:
Q. What's involved in becoming a CLIA certified lab?
A. A CLIA certified lab is allowed under CLIA to develop their own diagnostic tests based on components. They're responsible for validating that test.
Q. How is permission acquired from C.A.P.?
A. C.A.P. audits laboratories.
Q. Is there an application procedure?
A. In some instances.

Q. Does Illumina have a CLIA certified lab?
A. Yes.
Q. Did it apply?
A. Yes.
Q. What was that procedure?
A. I'm not aware of the detailed procedure.
Q. After the acquisition of Epicentre, how are the products that Epicentre sells branded?
A. I'm not sure.
Q. Who would know that?
A. I'm not sure.
Q. Would Karen Possemato know?
A. I -- I don't know for sure.
Q. Could I find that out by visiting the website?
A. Are you asking me if you can find out who would know --
Q. No.
A. -- on the website?
Q. How they're branded?
A. I don't know.
MR. HANKINSON: I'd like to mark something

as Exhibit A.
(Whereupon, O'Grady Exhibit Number A was marked for identification by the Deposition Officer and is attached hereto.)
BY MR. HANKINSON:
Q. Ms. O'Grady, when you get it, would you take a look at Exhibit A.
It's an article found on GenomeWeb with a date of August 27, 2014. And the title is "Illumina's Pharma Deals Aim to Bring Universal MiSeqDx-based CDx through FDA Clearance."
(Document reviewed by the witness.)
BY MR. HANKINSON:
Q. Do you see that?
A. Yes.
Q. I'd like to call your attention to paragraph 4, and specifically the last three sentences beginning "A key difference..."
Are you with me?
A. Yes.
Q. And here there's a quote that's attributed

to you; is that right?
(Document reviewed by the witness.)
THE WITNESS: Yes.
MR. HORNE: Lacks foundation
BY MR. HANKINSON:
Q. I'll go ahead and read it, and then we can talk about it.
"'A key difference in using the MiSeqDx for oncology purposes is that it will need to be cleared for use on formalin' -- it's f-o-r-m-a-l-i-n, hyphen, 'fixed paraffin,' p-a-r-a-f-f-i-n, hyphen, 'embedded tissue,' O'Grady said.
"Currently, it is cleared only for targeted sequencing of DNA from whole blood. It's use also must be expanded to include the detection of somatic," s-o-m-a-t-i-c, "rather than germline," g-e-r-m-l-i-n-e,

"variants."
Did I read that correctly?
A. Yes.
Q. This quotation is discussing a use of MiSeqDx for oncology purposes that's different from the one that had been FDA cleared before?
Do I have that right?
MR. HORNE: Lacks foundation.
THE WITNESS: Can you restate that question, please?
BY MR. HANKINSON:
Q. Sure.
There's a use on formalin-fixed paraffin-embedded tissue that is needed to be cleared, and there are prior uses of the MiSeqDx that had already been cleared by the FDA; right?
A. Can you -- I -- I don't understand what -- what you're saying it's needed for.
Q. Well, you say it will be -- "it will need to be cleared" in your quote.
A. Yes.
Q. And so I'm trying to use your words.

A. Okay. I'm -- I'm sorry. I still don't --
MR. HORNE: I'm going to object.
There's no quote here, so -- I don't see quote marks on there, so I don't know if that is her language or not.
That's my objection for lack of foundation.
BY MR. HANKINSON:
Q. There's a use of the MiSeqDx that were cleared already prior to the need to be cleared for use on formalin-fixed paraffin-embedded tissue?
That's what I'm asking.
A. The -- the -- I -- that -- that's what this quote says. That's what this article at GenomeWeb says.
Q. And it's inaccurate, is that what you're saying?
A. It's very specific to a particular use of the technology.
Q. Would Illumina's customers for the MiSeqDx be interested in details as specific as this when they're purchasing and using Illumina's products?

A. I -- I don't know if our customers would -- I -- I don't know.
Q. Wouldn't they have to be if they're operating a CLIA certified lab?
MR. HORNE: Argumentative.
THE WITNESS: I don't -- I don't understand the question.
BY MR. HANKINSON:
Q. Well, they're not going to use a product for a purpose for which it hasn't been cleared; right?
That would endanger --
A. That's not correct.
Q. Okay. Please correct me.
A. Molecular labs in a CLIA environment can develop their own tests with components that are not FDA cleared.
Q. Why would this particular use, then -- to quote you -- "need to be cleared"?
A. To --
MR. HORNE: Just object; lacks foundation.

THE WITNESS: To establish claims to support a pharmaceutical drug application.
BY MR. HANKINSON:
Q. Another consumer of Illumina's products are -- excuse me.
So are we talking about clinical trials?
A. Oh. Yes.
Q. And who's performing the clinical trials?
A. A clinical trial would be performed at a CRO, clinical research organization, or a hospital laboratory governed by Illumina and/or a pharmaceutical company for this particular application discussed in this article.
Q. Who are the consumers for Illumina's own CLIA certified lab?
A. That's a good question.
There are several consumers of Illumina's CLIA certified lab. I don't -- one example would be the Medical College of Wisconsin for rare pediatric disease.
Q. It sounds like you're still answering.

A. That's one example.
Q. Is it only a handful of consumers or --
A. No.
Q. -- there's different types?
A. There's different types --
Q. Could you --
A. -- of consumers.
Q. -- list the types of consumers?
MR. HORNE: Lacks foundation.
THE WITNESS: I'm actually not sure of all of the consumers, which is why I said it's a good question. I -- I don't know all of them.
BY MR. HANKINSON:
Q. Could you list the ones you know, the types?
A. I'm -- I'm -- I'm aware of the use of our CLIA sequencing services for rare pediatric disease for an offering that we call "Understand Your Genome," and also to pharma.
Q. And what are the products and services that the Illumina CLIA certified lab purchases?
A. I don't know what they purchase.

MR. HANKINSON: I'm going to use an exhibit. The rest of my exhibits have a number that's already been assigned to them --
THE WITNESS: Okay.
MR. HANKINSON: -- in the case, and I'd like to use that same exhibit number to avoid confusion.
THE WITNESS: Sure.
MR. HANKINSON: Does that work for you guys?
MR. HORNE: Yeah. Why don't you just say what's previously been marked?
MR. HANKINSON: Yeah.
MR. HORNE: Because they are all of record with the board; right?
MR. HANKINSON: Uh-huh.
MR. HORNE: So let's just use that number.
MR. HANKINSON: Yeah. So I'd like to mark this as Deposition Exhibit 303 as well.
(Whereupon, O'Grady Exhibit Number 303 was marked for identification by

the Deposition Officer and is attached hereto.)
DEPOSITION OFFICER: Okay.
MR. HORNE: I'm not here to run your deposition. As far as I'm concerned, you can just say, "I'll hand you what's previously been marked."
I don't know if you need to mark it again, but I'll leave it to you.
DEPOSITION OFFICER: Here you go.
MR. HORNE: Thanks.
(Document reviewed by the witness.)
BY MR. HANKINSON:
Q. Exhibit 303 is a document that's referenced in the declaration that you submitted in this case; right?
A. Yes.
Q. What is Exhibit 303?
A. It's a document that we refer to as a "Launch Package." It's a compilation of information to help a salesperson communicate about our products.
Q. Was this document used for training a

sales team on how to position BeadXpress technology to prospective customers?
A. Yes.
Q. And the -- this launch package pertains to BeadXpress system and VeraCode technology; right?
A. Yes.
Q. There's an acquisition of a company called -- was it CyVera? C-y-, capital V, -e-r-a,
A. I'm not sure if the capital is there or not, but it is CyVera, and it is spelled that way.
Q. And that occurred in roughly in 2007?
A. No, that --
Q. 2005?
A. Yes.
Q. And in 2007 the BeadXpress system and VeraCode technology were being launched with this launch package; right?
A. This launch package was developed in 2007.
Q. And when this was used to train the sales team to position the BeadXpress technology to prospective customers, the prospective customers were laboratories; right?

A. Yes.
Q. And any other prospective that were not laboratories?
A. Yes.
Q. And what were those?
A. We marketed the technology to prospective diagnostic development partners.
Q. Other companies?
A. Other companies, yeah.
Q. Would the other companies purchase this platform or just be licensed to use it through Illumina?
A. Potentially, both.
Q. And who at the laboratories -- well, what type of laboratories?
Are there multiple types?
A. Yes.
Q. And what types?
A. Molecular diagnostics laboratories, academic laboratories, agriculture laboratories.
There are probably others that I can't remember right now.

Q. Academic laboratories would be purchasing the system and technology for research purposes; right?
A. Yes.
Q. And in 2007 molecular diagnostic laboratories who wanted to purchase and use the BeadXpress system and VeraCode technology could use it to develop their own lab-designed tests; right?
A. A lab-developed test.
Q. Lab-developed test -- or LDT?
A. Yes.
Q. And using the technology and system in an LDT would be the only way at that time for a molecular diagnostic lab to use it for diagnostic purposes; correct?
A. Yes, in 2007.
Q. I have to remark that this launch packet to train the sales reps is very long and detailed.
MR. HORNE: Argumentative.
MR. HANKINSON: What's that?
MR. HORNE: I said, "Argumentative."
MR. HANKINSON: I think we can all agree

on that.
BY MR. HANKINSON:
Q. The -- how big is the sales team that was trained using this?
A. I don't remember.
Q. On the order of ten people or on the order of 100 people?
A. I don't remember the size of the sales force in 2007.
Q. Could it have been more than 100?
A. I'm not -- I'm not sure. It may be.
Q. And would you have been considered a part of that or not?
A. Are you asking me if I was part of the sales team?
Q. Yeah.
A. I was a product marketer.
Q. And should that mean to me that you were not part of the sales team?
A. I was part of marketing; I was not part of sales.
Q. Did the sales team have a required science

or technology background at the time?
A. I don't know.
Q. Was it preferred that they did?
A. I don't know.
Q. If information is contained in this launch package which was used to train the sales team on how to position the BeadXpress technology to prospective customers, can we agree that it is information that might interest or be asked about by those prospective customers?
MR. HORNE: Lacks foundation.
THE WITNESS: I --
MR. HORNE: Vague.
Go ahead.
THE WITNESS: There's information in this package that we would expect customers to ask. I think there's a --
BY MR. HANKINSON:
Q. And that's why it's in --
A. -- "Frequently Asked Questions" section --
Q. Uh-huh.
A. -- intended to answer questions that a

customer may have.
Q. Uh-huh. And if it's in here, it's to enable the sales team to interact successfully with those potential customers; right?
That's the purpose of putting information in this launch package?
A. Yes.
Q. The target market -- if you can turn to page 4 under the heading "Target Market," sentence two.
A. Uh-huh.
Q. The target market for the BeadXpress Reader was a:
"...combined market serving genotyping, gene expression, and protein analysis..."
Right?
A. Yes.
Q. And that matches up with the three analytes that you listed for me earlier; right?
A. Yes.
Q. DNA, RNA --

A. And protein.
Q. -- and protein.
And there's an issue in the market of sort of different levels of multiplexing; right?
A. I don't understand.
Q. Well, multiplexing and the level to which a system can multiplex seems to be a sales point, and certain people need kind of a higher multiplexing level and certain don't.
And then there's price differences between the two?
Am I oversimplifying it?
A. The system was capable of a variety of multiplexing levels, and there were applications where that was relevant.
Q. And lower down under "Target Market," there's a bullet pointed list that has the preface:
"The target market and customer base include."
A. Uh-huh.
Q. Right?
A. Uh-huh.

Q. And there's four types of customers listed; right?
A. Yes.
Q. The first is:
"Researchers interested in focused analysis of markers of interest following a larger microarray discovery project.
"These include existing Illumina customers owning a BeadArray Reader, in addition to other competitive platforms."
That's the first bullet; right?
A. Yes.
Q. "Researchers" means people interested in answering questions for the purpose of research, as opposed to diagnostics; right?
A. Yes.
Q. And then the second bullet is:
"Researchers interested in performing SNP genotyping analysis of a broad range of multiplex

reactions, typically higher than a 3-plex reaction, and/or a high volume of samples per project."
That's the second bullet; right?
A. Yes.
Q. And, again, it's researchers as opposed to people using this for diagnostics; right?
A. Yes.
Q. Then the third type of customer in the customer base for the BeadXpress system and VeraCode technology in 2008 were:
"Researchers interested in developing their own protein-based multiplex assays and/or genotyping assays."
Right?
A. Yes.
Q. And, again, those are researchers who are answering research questions as opposed to clinical diagnosticians answering a clinical diagnosis question; correct?
A. Yes.

Q. And then the fourth part of the customer base for the BeadXpress system and VeraCode technology in 2008 consisted of:
"CLIA high complexity certified laboratories interested in developing laboratory-developed tests using RUO products for multiplex assays."
Right?
A. Yep. Yes, that's what it says.
Q. What is the meaning of "high complexity" in the phrase "CLIA high complexity certified laboratories"?
A. "High complexity" is a type of CLIA certification, and molecular laboratories fall under the high complexity category of CLIA.
Q. Did you say "molecular categories"?
A. I said, molecular diagnostics --
Q. Uh-huh.
A. -- falls under the CLIA high complexity type of a CLIA lab. All molecular testing happens in a high complexity laboratory.

Q. So it's all molecular testing falls under the category of high complexity?
A. Yes.
Q. Are there like additional restrictions or regulations to be a high complexity CLIA certified lab?
A. The -- the main one that has to do with molecular testing is the issue of contamination -- molecular contamination.
So having a pre- and a post-amplification, the difference between a CLIA high complexity lab and a moderate-complexity lab is very, very simple assays that don't have that risk.
It could be run in a moderate complexity environment, which is more like a -- a doctor's office.
Q. So a middle level -- a middle complexity -- is that what you said, "middle complexity"?
A. I -- I'm most familiar with the high complexity environment.
I know that there's also a CLIA waived,

which is like a doctor's office.
Q. So let me ask: A doctor's office would not be a high complexity CLIA certified lab?
A. No.
Q. It would be an actual laboratory; right?
A. Yes.
Q. And when you say, "pre- and post-amplification, potential molecular contamination," are you talking about something that would affect the results of a test, or contamination like people could get sick?
A. The active detecting molecules frequently requires amplification, making multiple copies of DNA, and that process has a risk of contamination from molecules around a lab.
So all molecular diagnostic labs are required to do their testing in a CLIA high complexity environment to control for risk of a wrong result.
Q. Is it --
A. And that's what C.A.P. regulates.
Q. Is it equipment or procedures or both

that are required to protect against that contamination?
A. The -- the laboratory process and governance that a CLIA lab has to put in place controls for it.
Q. It does sound highly complex.
A. That's why, yes.
Q. The use of "RUO" in the fourth bullet on page 4, does that stand for "Research Use Only"?
A. Yes.
Q. So to the extent in 2008 that the target market and customer base for the BeadXpress system and VeraCode technology included laboratories for diagnostic purposes, it would only be in the context in which such a laboratory used a research-use-only product to develop a laboratory-developed test; correct?
A. I -- I'm sorry. I had a hard time following what you just said. Could you please repeat it?
Q. To the extent, in November 2008, that a laboratory might be interested in purchasing the

BeadXpress system and VeraCode technology that this launch package is about, it would be only to use that product and technology, which was a research-use-only product and technology at the time, in developing a laboratory-developed test which would then be used for diagnostic purposes --
MR. HORNE: Lacks foundation.
///
BY MR. HANKINSON:
Q. -- right?
MR. HORNE: Sorry.
THE WITNESS: I -- I don't know.
BY MR. HANKINSON:
Q. "RUO" means research use only?
A. Yes.
Q. This is the fourth type of potential customer in the customer base; right?
A. Yes.
Q. And the first three were research applications as opposed to diagnostic applications; right?
A. Yes.

Q. And the fourth one might have something to do with diagnostic applications; right?
A. Yes.
Q. And that's the only part of the customer base where it might have something to do with diagnostic applications at that time --
MR. HORNE: Lacks foundation.
BY MR. HANKINSON:
Q. -- right?
MR. HORNE: Sorry.
///
BY MR. HANKINSON:
Q. As expressed in this launch packet; right?
A. No.
Q. Is there a customer not listed in the launch package?
A. The four bullets that were listed here represent the lowest hanging fruit for a sales representative; are not an exhaustive list of potential customers of the platform.
Q. What about -- does this include all the

laboratories that are included in the potential customer base?
A. No.
Q. What other laboratories would there be?
A. I described previously agriculture testing labs, diagnos- --
Q. Those would be --
Go ahead.
A. -- diagnostic development partnerships, PhRMA.
There are other types of labs that were customers of Illumina than the four listed on this.
Q. Did you say "those were" or "there are" other besides those three?
A. Those are examples of other customers.
Q. Are there any other examples of other customers?
A. There was possibly other -- other customers. Those are three examples I can come up with.
Q. The only way for a laboratory in November

2008 to use the BeadXpress system and VeraCode technology for a diagnostic purpose would be to develop an LDT; is that accurate?

A. I don't know of another way.

Q. And --

A. I'm sorry. I'm going to strike that.

A customer could choose to solicit their own FDA submission if they wanted to.

And outside of the United States, the regulations are different.

Q. And that's complete -- your answer is complete?

A. I'm not aware of another way.

Q. And that is true of any laboratories doing agriculture testing, any laboratories at other businesses that you might partner with for the development of a diagnostic test, and for pharmaceutical laboratories as well; correct?

They'd either have to do an LDT or seek some sort of other FDA approval or clearance in order to use the technology in a diagnostic application?

A. In the United States, that is correct for most types of diagnostic tests.

Q. And what are the types of diagnostic tests that would be exceptions to that?

A. Well, one example would be preimplantation genetic testing; it's not currently regulated.

They're -- they're examples of types of tests that are not regulated.

Q. Any others?

A. Not that I'm aware of.

Q. When you say "preimplantation genetic testing," you are talking about genetic testing of a -- what are you -- what is the -- is it like in utero?

A. Testing of embryos prior to implantation.

Q. It's a little bit odd because it's sort of chicanery whether that's diagnostics; right?

The reason that it's not regulated in the way that diagnostics are is because it's not considered diagnostics; right?

A. Depending.

MR. HORNE: Lacks foundation. It's argumentative.

BY MR. HANKINSON:

Q. By the FDA?

A. I'm not aware of what the FDA thinks about that.

Q. You don't have any reason to disagree with that?

A. I'm -- I'm not aware of the FDA's current thinking on that field.

Q. It's not currently regulated?

A. It is not currently regulated.

MR. HORNE: You need a little while longer on this document?

We've been going an hour and a half. I would suggest a break, but if you've got a few more questions, we can hold off.

MR. HANKINSON: I might go on and on. You want a break?

MR. HORNE: Yeah. Why don't we do that, then?

DEPOSITION OFFICER: Off the record.

///

(Whereupon, a recess was held from 9:31 a.m. to 9:45 a.m.)

DEPOSITION OFFICER: Back on the record.

BY MR. HANKINSON:

Q. When a customer purchases a product or service from Illumina's CLIA high complexity certified laboratory -- first of all, is it a product or a service or can it be either?

A. Our CLIA certified lab offers services.

Q. And not products?

A. And not products.

Q. When a customer requests a service from that lab, what is the process?

A. An individual would require a doctor's order and a consent. Their sample is sent to Illumina; we test it and provide a report back to their physician.

Q. What physical form or electronic form does the report take?

A. I'm -- I'm not aware of that.

Q. You don't know if it's e-mailed or if it's

sent by --
A. I don't know.
Q. -- paper?
A. I don't know.
Q. Do you know what's in those reports?
A. No, I don't know exactly what's in the report.
Q. Do you know what they look like?
A. No, I don't.
Q. Do you know how they're branded?
A. "Illumina." They're branded with Illumina's name.
Q. In what sense?
A. All of our products and services are branded with "Illumina."
Q. So you're taking the general proposition that everything is branded with "Illumina," and then you're concluding, even though you don't know what the report looks like, that it is also branded "Illumina"?
A. We have a policy that all of our labels and materials are branded "Illumina."

Q. What about subsidiaries that are still --
A. I'm sorry.
I want to -- I just want to clarify that.
It's a -- it's not a policy, it's a guide.
Q. So it's a guide that they should be?
A. Our -- our -- our branding book says that all things are labeled with "Illumina."
Q. The guide that you're referring to is not referenced in your declaration, is it?
A. No.
Q. Do you have any knowledge of whether that guide has been provided by Illumina to Meridian in the process of discovery?
A. No, I don't know.
Q. Is that guide your basis for saying that the report that comes out of the CLIA high complexity certified lab run by Illumina is branded with "Illumina"?
A. That would inform my assumption.
In addition to that, I have been at

presentations where we are speaking about our services, and images of the report have been presented that are branded "Illumina."
Q. So you have seen them?
A. I -- I have seen an image of a report. I have not looked at the details of the -- the result.
When you asked me about what's in the report, I'm assuming you mean what is the detail of the result, and I -- I don't know the exact details of that.
Q. So you're talking about like a slide deck? It has a photo of a report?
A. Yes.
Q. And what, if anything, did you do to confirm that that was an accurate image of an actual report as opposed to something created for the slide deck?
A. Nothing.
Q. When the individual -- excuse me.
When the sample is sent to the CLIA high complexity certified lab run by Illumina, who sends that sample?

A. I'm not sure.
Q. What entity does it come from?
A. It --
Q. The patient?
A. No.
Q. Does the patient send it?
A. No.
Q. Who sends it?
A. The -- the test order has to come from a physician, and -- and someone needs to do a blood draw. And whoever does that, I'm assuming sends the sample.
Q. The test order that comes from the physician is essentially -- I don't know -- "prescription" is not the right word, but the doctor has to order that the test be done; right?
A. Our -- our CLIA service is only offered when a physician orders the test.
Q. But the physician doesn't send the test order to you? The blood's drawn by someone and then that is sent to you along with the physician's order that the test be done?

Do I have that accurately?
A. I -- I don't know.
Q. You're not sure?
A. I -- I don't know the exact details of how the test order and the blood comes to Illumina.
Q. And that information, then, is not in your declaration that was submitted in this case?
A. I -- I don't think so.
Q. You wouldn't have put something in your declaration that you didn't think you knew?
A. Right. No, I wouldn't.
Q. So are you not sure whether the physician makes the actual order for the service from Illumina's CLIA certified lab, or whether it is a laboratory that's separate from the physician that does the blood draw?
You just don't know one way or the other?
A. I -- I know that a physician has to order the test. I don't know if the physician or some other blood-draw location takes the blood and sends it to Illumina.
Q. So do you know who the customer of

Illumina's CLIA certified lab is -- or who --
A. I know --
Q. -- those customers are?
A. I know of some of the customers of a Illumina's certified lab.
Q. And you said one is the Medical College of Wisconsin for rare -- in relation to rare pediatric disease; right?
A. Yes.
Q. And so when that customer wants to use the service, who -- who's the individual that would interact with Illumina to make that happen?
A. I don't know.
Q. Do you know what that person's position is?
A. I'm -- I'm sorry?
Are you asking me about the Illumina people, or are you asking me about Medical College of Wisconsin?
Q. Medical College of Wisconsin.
A. Can you ask the question again?
Q. Sure.

When Medical College of Wisconsin wants to get a service from Illumina's CLIA certified lab, who at Medical College of Wisconsin makes that happen?
A. I don't -- I don't know who there is ordering the test.
Q. Do you know the position or positions of the person or people who would be ordering the test?
A. I do not.
Q. Do you know if the person or people who are ordering the test are the customer of Illumina's CLIA certified lab, or if someone else makes the decision and the person who sends the order for the test is just implementing that afterwards?
A. The test -- our -- our CLIA service is implemented in our own laboratory.
Q. Right.
A. So the -- unlike a product, it -- it's a service.
Q. Uh-huh.
A. A physician orders it and receives the

report. They're not implementing the test in their own lab.
Q. Right.
A. It's a service.
Q. And Illumina doesn't do it randomly, they do it by request; right?
A. Yes.
Q. So -- I mean, maybe I'm oversimplifying, but somebody has to ask for it?
A. Yes.
Q. And you don't know who that person is.
And what I'm asking is: Do you know whether whoever is sending the test is the person who is making the decision to utilize Illumina's service with its CLIA certified lab or not?
A. I don't know.
Q. What other examples of customers of Illumina's CLIA certificate lab, other than Medical College of Wisconsin, do you know?
A. I don't know of any other specific customers.
Q. Are any of Illumina's products or services

used in a conventional physician's office as opposed to a laboratory?
A. I -- I don't understand what you mean by a "conventional physician's office."
Q. A doctor's office.
A. You're -- you're asking me if any of our products are used in a conventional physician's office?
Q. Yes.
A. I -- I don't know. I don't know.
Q. You don't consider the doctor's offices to be part of the customer base of Illumina's platforms, consumables, or services, do you?
A. Physicians order our CLIA high complexity tests.
Q. Right.
But you don't know whether they ask for them or whether they order that a test be done and somebody else orders it from the CLIA high complexity certified lab?
A. I --
Q. We were just going over that.

A. I don't know the process for how these tests are ordered.
Q. Do you --
A. I'm not involved with that.
Q. Do you know whether a doctor requests Illumina's lab as opposed to some other lab?
A. Do I? I -- I don't know.
Q. Because I've been ordered to get a blood test, and then I have to go to like some third party and they draw the blood.
A. Uh-huh.
Q. And -- and I guess what I'm hearing is, you don't know whether like Quest, or whoever is drawing the blood, is choosing to use Illumina's CLIA certified lab or whether the doctor is choosing to use Illumina's certified lab or whether it's somebody, you know, higher up at Quest or the other third party who like has a relationship with Illumina's lab.
That's what I'm trying to ask.
A. Illumina offers a few services in a -- in a CLIA lab. We offer non-invasive prenatal testing

and whole genome sequencing, and I'm not aware of how those products are ordered and sold.
Q. So when I asked whether any products or services were used -- excuse me.
When I asked you whether any products and services of Illumina were used in a doctor's office --
A. Uh-huh.
Q. -- you answered doctors order the tests that are then sometimes done in CLIA's certified lab.
Are there any physical products that would go to a doctor's office -- to be purchased by a doctor, not in a laboratory setting?
A. I'm not aware if as part of those services, if a component is shipped to a physician to -- to enable that test. I don't know.
Q. I thought a report went to the doctor?
A. If -- if -- I don't -- I do not know if there's any component that goes to the physician to enable a sample collection.
Q. So you don't know whether such a component

would be branded or not because you don't know even if it exists; is that accurate?
A. I -- I'm -- I'm not involved directly with their services business. I -- I don't have the details of that.
Q. Could you turn to Exhibit 303 --
A. Uh-huh.
Q. -- and flip to page 5.
On page 5 there's a table of the top competitors of the BeadXpress system and their platforms; right?
(Document reviewed by the witness.)
THE WITNESS: Yes.
BY MR. HANKINSON:
Q. The most challenging competitor to BeadXpress in late 2008 was Luminex; correct?
MR. HORNE: Vague.
THE WITNESS: I don't think I referred to Luminex as the most challenging competitor.
BY MR. HANKINSON:
Q. Did you author Exhibit 303?
A. No, Mickie Henshall did.

Q. Did you have input into it?
A. At the time that it was updated in two thousand -- in 2008, I assisted in that modification.
Q. At that time were you aware of the entire contents of the document or just parts that were being modified?
A. I used this document many times.
Q. So you're aware of everything in it?
A. I -- yes, I read it many times.
Q. And when you assisted in the updating, if there was anything in here that was inaccurate, would you have brought that to the attention of Ms. Henshall or someone else?
A. If I noticed something was wrong, I would have fixed it.
Q. And would that have been part of your duties?
A. I don't know -- yeah. I mean, I don't know if it was my duty or not, but I would have done it. I would have corrected an error.
Q. And who -- I assume Ms. Henshall signed

off on this document and took responsibility for its final contents, because her name as on the cover of it.
Do I have that correct?
A. She -- I -- I don't recall what the sign-off process was when it was re-issued.
Q. There were multiple people who would have reviewed this at Illumina and signed off on it prior to it being considered complete?
A. I don't -- I don't recall the review process prior to its distribution.
Q. But at least you and Ms. Henshall reviewed it?
A. I don't recall the review process before this was redistributed.
Q. If you look at page 5 --
A. Uh-huh.
Q. -- third sentence.
A. Yeah.
Q. (READING):
"While each competitor has had success in the market, it is

Luminex that poses the most direct challenge to BeadXpress, especially in terms of the multiplexing technology, a very large install base" --
A. Uh-huh.
Q. (READING):
"-- and a formidable menu of tests."
Did read that right?
A. Yes.
Q. So I had asked you whether it was the most challenging competitor, but perhaps a better question would be: Was Luminex the competitor that most directly competed with the features -- that had a product that most directly competed with the features that BeadXpress was offering?
A. Yes, that's true.
Q. So it was the closest thing to BeadXpress on the market at that time?
A. Yes, that's true.
Q. The table on page 5 has a column for

"Illumina BeadXpress," and right next to that, a column for "Luminex"; right?
A. Yes.
Q. The instrument cost of the Illumina BeadXpress at the time was 98,500 dollars; right?
A. Yes.
Q. And Luminex, there's a range listed of 20,000 to six hundred -- to 65,000 dollars for its competing system?
A. That's -- that's what it says.
Q. The competing system was the Luminex 100 System, which was launched in 1999; right?
A. I do not recall when it was launched.
Q. I'll refer -- maybe it will refresh your memory if you could check the fourth sentence of the page, starting with "Since the commercial launch..."
A. Okay, yes. Thank you.
Q. And that refreshes your memory that the Luminex 100 --
A. Yes.
Q. -- System was launched in 1999?
A. Yes.

Q. And the Luminex 100 System was, like BeadXpress, used in genotyping, gene expression, kinase selectivity, protein, and immunoassays?
A. Yes, it was --
Q. And Luminex --
A. -- capable of all those things.
Q. And Luminex, like Illumina, also reached partnership agreements with other research and diagnostic companies; right?
A. That's correct.
Q. Which is similar to the customer base of the BeadXpress system and VeraCode technology that we discussed earlier today; right?
A. I'm sorry? Can you ask that again?
Q. Yeah.
That's similar to the customer base that we discussed earlier today for Illumina's BeadXpress system and VeraCode technology?
A. Our customer base was -- we -- we had similar customers. We also had additional customers than -- than Luminex did.
Q. And like Illumina's customers, some of

Luminex's customers partnered to develop and market their own branded assays to run on the Luminex system; right?
A. It is correct that Luminex partnered with other companies to offer their own tests.
Illumina did not offer tests that were branded by other partners.
Your -- I think your question said Luminex did that like Illumina. But Luminex did it.
I'm not agreeing that Illumina did that.
Q. Illumina had partnerships with other companies to develop -- for those companies to develop assays?
A. That's correct.
Q. When there's an LDT in 2008 developed by using the BeadXpress in a customer's laboratory --
A. Uh-huh.
Q. -- what physical form does that LDT take?
A. I don't -- I don't understand the -- the question. That's kind of --
Q. An LDT is a thing; right?

A. It's a service.
Q. It's a service?
A. Yeah, a lab-developed test is a service.
Q. So there's not a physical product that comes out of an LDT?
A. There are physical products that go into the process in the lab that results in a -- in a test offered by that lab.
A lab-developed test is a -- is a test service where a lab purchases equipment and consumables to offer that service in their lab.
Q. Uh-huh. And so when you say that unlike Luminex, Illumina's -- excuse me.
So when one of Illumina's customers in 2008 developed an LDT, the output would be data?
A. A test report.
Q. A test report?
A. Yes.
Q. Would it be sent in some form to whoever ordered the test?
A. To a physician, most likely.
Q. And that would be sent by the lab that is

Illumina's customer to the person who ordered the test; right?
A. Yes.
Q. They wouldn't forward it to Illumina, and then Illumina would forward it to the person --
A. Oh, no.
Q. -- who ordered the test?
That would be ridiculous; right?
MR. HORNE: Argumentative.
BY MR. HANKINSON:
Q. Well, it's just because you said, "Oh, no" as if it would be calamitous.
A. We -- no, Illumina would not consume their data prior to it being presented to whomever the customer is of their lab service.
Q. And Illumina would not control the contents of the report that went from the lab that was Illumina's customer to the person who ordered the results of the LDT?
A. They would not control that, no.
Q. Illumina would also not control any branding associated with that report; correct?

A. No, they would not control that branding.
Q. Are LDTs sometimes referred to as "homebrews"?
A. Yes.
Q. Is there anything else that's included in the term "homebrews"?
A. I'm -- I'm not aware of all of the uses of that term.
Q. When you and Ms. Henshall used the term "homebrews" in the launch packet, that is Exhibit 33 --
A. Uh-huh.
Q. -- did you mean it to be synonymous with LDTs?
A. Yes.
MR. HORNE: You mean Exhibit 303?
MR. HANKINSON: Excuse me.
303.
BY MR. HANKINSON:
Q. And your answer is the same?
A. Yes.

Q. In the "Pricing Restrictions" row of the table on page 5 of Exhibit 303, under the columns for "Illumina BeadXpress" and "Luminex," there is a reference to "homebrew" in both columns, both for Illumina BeadXpress and for Luminex; right?
(Document reviewed by the witness.)
THE WITNESS: Yes.
BY MR. HANKINSON:
Q. In the column for "Illumina BeadXpress" --
Did you get a spelling for "BeadXpress"?
DEPOSITION OFFICER: I did.
MR. HANKINSON: Okay.
DEPOSITION OFFICER: Thank you.
BY MR. HANKINSON:
Q. In the column for Illumina BeadXpress it says:
"Customers developing homebrews will need to optimize reagents and workflow to determine pricing (like Luminex)."
Did I read that correctly?
A. Yes.

Q. Can you explain in what way that was like Luminex?
A. The -- both technologies had varying multiplex capability, and so a single analyte assay would cost a different amount than a multi-analyte test or assay.
Q. If you were using a lower level of multiplexing, then you wouldn't be maximizing the capabilities of reducing the price of the test?
A. That's incorrect.
Q. Okay. Please correct me.
A. We offered beads in such a way that a customer could run a single analyte test in a cost-effective way.
Q. The cost per test would scale up and down depending on multiplexing in the same way that it would with Luminex's product?
Now do I have that correctly?
A. Yes, I -- yes, that's true.
Q. Then in the row that says "Number Apps (GE, et cetera)," what does "Number Apps (GE, et cetera)" mean?

A. It's talking about the number of applications. I -- I don't recall what "GE" stood for, but I'm going to assume it meant "gene expression, et cetera."
Q. And --
A. The applications the system was capable of.
Q. And in the column for "Illumina BeadXpress," the applications that are listed are "genotyping protein assays" and "gene expression"; right?
A. That's what it says, yes.
Q. And the same three applications, although in a different order, are found in the column under "Luminex"; right?
A. Yes, that's right.
Q. So in late 2008, Illumina BeadXpress and Luminex, it says, 100 system were offered to an overlapping pool of customers, each at a price within the tens of thousands of dollars, each sometimes used in developing homebrews or LDTs, and each with the potential applications of genotyping

protein assays and gene expression.
Did I summarize that correctly?
A. Yes.
Q. If you could turn in Exhibit 303 -- excuse me -- still on page 5 of Exhibit 303, "Sequenom" is another competitor to Illumina BeadXpress that's listed; right?
A. Yes.
Q. And that's S-e-q-u-e-n-o-m; right?
A. Yes.
Q. Is that still a competitor of Illumina?
A. Yes.
Q. Illumina offers the MiSeq product which ends in S-e-q; correct?
A. Yes.
Q. And also the HiSeq product that ends in S-e-q?
A. Yes.
Q. And at one point Illumina offered a research-use-only assay called "GoldenGate"; is that accurate?
A. Yes.

Q. And in 2008 Sequenom offered an iPLEX gold assay; is that right?
A. Yes.
Q. Could you turn to page 14 of Exhibit 303.
Under "Ordering Information" there's a reference to catalog numbers.
Do you see that?
A. Yes.
Q. Could you explain to me what the catalog is that the catalog numbers are in?
A. Um –
Q. Or if that's a stupid question, just explain why.
MR. HORNE: And I won't object "argumentative."
THE WITNESS: It's a -- there's – those numbers are a way for us to refer to our -- our products on the web and in different systems within the organization.
BY MR. HANKINSON:
Q. Customers can use these catalog numbers to order the products that they want; is that

accurate?
A. Yes.
Q. And they see them on the web sometimes, at least?
A. Sometimes they're presented on the web.
Q. Can you order directly from the web?
A. Yes.
Q. Can you also order by calling your sales rep?
A. Yes.
Q. Do you have any sense of what percentage of the sales are made through the web as opposed to through sales reps?
A. I don't know.
Q. Do you have any sense of whether laboratory customers typically purchased through a sale rep or through purchases on the web?
A. I'm -- I'm not aware of how -- what -- what frequency of orders are online versus to a sales rep.
Q. Do laboratory customers typically have a purchase-order system that they go through?

A. Yes.
Q. So when a lab customer purchases the product from Illumina, the lab director is the person who makes the final decision about whether to order?
Is that accurate or not accurate?
A. I'm sorry? Can you ask that question again?
Q. Yeah.
When a laboratory customer orders a product from Illumina, does the lab director make the final decision about whether to make that purchase?
MR. HORNE: Vague, lacks foundation.
THE WITNESS: I don't know if all cases it's the final decision. The lab director is a key stakeholder in the decision-making process.
BY MR. HANKINSON:
Q. Who are the other key stakeholders in the decision-making process?
A. A medical director, hospital administration. There may be others.

Q. When it's the hospital administration, is that a purchasing department?
A. I -- I was -- I was thinking higher up in the organization, like president. And also -- I mean, yes, purchasing agents are involved in the process.
Q. So at times the president of the hospital is involved in deciding whether to purchase a product from Illumina?
A. I'm sorry?
Were you saying from Illumina or in general?
Q. From Illumina.
A. Yes, in some cases that could be the case.
Q. Is the medical director usually somebody who's placed within the laboratory or somebody who is outside of the laboratory?
A. I'm not sure if they are necessary to reporting into a laboratory organization, but that would be a stakeholder that would provide feedback on the medical need.
Q. Have we covered all of the stakeholders of

which you are aware in decisions among customers to purchase Illumina's products?
A. I -- in that conversation I was really thinking about a clinical use.
There might be other stakeholders in different uses of the technology. Yeah, there -- there may be others --
Q. How --
A. -- based on different uses.
Q. How would that be?
A. Well, for -- for example, if we're talking about agriculture, it's a different set of stakeholders.
If we're talking about pharmaceutical partnerships, it's a different set of stakeholders that are deciding whether or not they want to use that technology.
Q. As opposed to a clinical use?
A. A clinical use, yeah.
Q. And so you're saying the stakeholders at places like that, agricultural and pharma partnerships, would be different stakeholders

because you're not dealing with the same stakeholders as in a clinical setting; is that right?
A. Yes.
Q. The prices of Illumina's BeadXpress system on page 14 -- actually, it's just one price for two different catalog numbers.
There's a "List Price NA_EU" that's 98,500 dollars; right?
A. Yes.
Q. Is that North America and Europe?
A. Yes.
Q. Oh, my God. I got it right.
And then there's "List Price ROW" that's 118,200 dollars; right?
A. Yes.
Q. What is "List Price ROW"?
A. "Rest of World."
Q. And the price of the BeadXpress system -- is the BeadXpress system no longer offered?
A. The BeadXpress system is no longer offered.

Q. It sounds like you wanted to say something else.
A. Well, it -- it was like a double negative. I didn't know how to -- whether to say "Yes" or "No" to your question, so I'm restating that the BeadXpress system is no longer offered.
Q. Thank you.
A. It -- it is, however, supported by the organization. There are people still using it.
Q. When did it -- when did it -- when was it discontinued?
A. I don't remember the exact date it was discontinued.
Q. Was it after 2009?
A. I don't recall.
Q. In late 2008, at the bottom of page 14 --
A. Uh-huh.
Q. -- there is also a "BeadXpress Starter Kit." The description actually goes on to page 15.
A. Uh-huh.
Q. And the starter kit has a North American and European price of 3,237 dollars; right?

A. Yes.
Q. And then at the time, there was a GoldenGate assay for research use only; right?
A. Yes.
Q. And the satellite kit for GoldenGate for BeadXpress would cost a customer 18,940 dollars in North America and Europe; right?
A. Yes.
Q. And the GoldenGate accessories kit, which was optional, would cost an additional 94,683 dollars in North America and Europe in 2008; right?
A. Yes.
Q. Different catalog codes apply to purchases of training services; right?
A. Yes.
Q. And if were look, for example, on page 17 at the VeraCode GoldenGate training kit --
A. I'm sorry?
Q. Excuse me.
I should --
A. Where are you again?

Q. On page 17.
A. Okay.
Q. And let's actually look at -- well, let me ask generally.
How often was training purchased alongside of a BeadXpress platform?
A. The catalog number of the BeadXpress platform included a one-day training. It was not common for a customer to order additional training because it was included in the instrument.
Q. So the training was not just recommended, but included in the price of purchasing the system?
A. That's right.
Q. The page -- at page 18 of Exhibit 303, we get to solve the mystery of the word that I was trying to remember earlier.
It's "oligonucleotide."
A. Okay.
Q. So on page 18 there begins a list of catalog numbers for "VeraCode Universal Capture Bead Set" where that's the description of the product for

many, many rows of this list of catalog numbers --
A. Yes.
Q. -- right?
A. Yes.
Q. And the only distinction in the description of the product -- excuse me.
What's the column that I'm referring to? The title of the product? The product name?
A. The VeraCode Universal Capture Beads.
Q. And is that the product name or the product title?
A. That's the -- the product name.
Q. So the product name for the following -- one, two, three, four, five, six, seven, eight -- nine pages, each with five or six products per page.
The product name is the same for each row, "VeraCode Universal Capture Bead Set," except that there's a different number at the end.
A. Yes.
Q. And it's a four-digit number in each case?
A. Yes.

Q. So there's at least three dozen different VeraCode Universal Capture Bead Sets that are differentiated in product name only by number --
A. Yeah.
Q. -- at the end; right?
A. Yes.
Q. And the next column over to the right, is that like a product description?
A. Yes.
Q. And so for the several pages, and over three dozen products that are titled "VeraCode Universal Capture Bead Set," the product description is also completely identical for each product except for a series of letters in parentheses in the middle of each description.
Do I have that right?
(Document reviewed by the witness.)
THE WITNESS: Yes.
BY MR. HANKINSON:
Q. And the series of letters in parentheses on the fourth line of each description for the VeraCode Universal Capture Bead Set sets out a

different combination of the letters T, C, G, and A; right?
A. Yes.
Q. And those are -- tell me what the vocab is. It has to do with DNA or RNA.
What are T, C, G, and A?
A. Those are bases of nucleic acid.
Q. And when you're sequencing DNA or RNA, it is expressed in series of these letters, T, C, G, and A; is that right?
A. I -- I just want to make sure there's not confusion that this is a sequencing solution.
Q. Sorry. Please explain it to me.
A. This -- this series of letters is a code that -- or a series -- it's an oligonucleotide that's attached to the bead.
And we refer to this series of bases as the unique Illumina code; it's the unique identifier for that bead.
Q. And what are the different beads with the different oligonucleotides used to do?
A. It's a capture sequence, so an assay

that's being developed to target some molecular signature would be tagged with a complement of this string of bases so that it could be captured and detected on the BeadXpress.
Q. And there -- these are a series of many dozens of preloaded oligonucleotides?
A. These oligos are attached to the beads before being received by a customer.
Q. And "Illumina Code" appears nowhere -- the words "Illumina Code" appears nowhere in the product description; right?
A. It does not appear in the product description.
Q. The series of the letters T, C, G, and A within the parentheses of each product description, are those of uniform length? They always have the same number of letters?
A. I -- I don't know for certain if they are exactly the same length.
I haven't counted them for every single one, but the combination and order has a certain melting temperature that's uniform.

I'm -- I'm sorry.
The bond that's created in that capture has a -- a certain melting temperature, and that combination of letters is -- is designed for that.
Q. And the series of letters, there's more than 20 letters in each series; right?
(Document reviewed by the witness.)
THE WITNESS: Sure. Yes.
BY MR. HANKINSON:
Q. And so looking at the product description, one can differentiate these products by checking the series of 20 letters to see if that order of the letters T, C, G, and A is the one that you want; is that right?
A. No.
Q. Its the only difference in this table; correct?
MR. HORNE: Lacks foundation.
THE WITNESS: This -- this table is designed for a sales rep and for a field-application scientist to help a customer.
The ordering information -- the last four

digits of the catalog number, being -5440, is the identifier of the bead.
BY MR. HANKINSON:
Q. So once you figure out which one you want, you can know the -- you can get the catalog number and just refer to it by that?
Is that what you're saying?
A. Yes.
Q. And the sales rep and field-application scientist would be available to assist a customer in, you know, selecting which 20-letter sequence oligonucleotide the customer needs?
A. The exact combination of -- of letters isn't really important to the customer.
We -- what's important to the customer is the 5440, for example. It's the first one on this page.
And the association of that to this line of letters is provided for service and sales as a reference.
Q. In order to help them when they're dealing with customers?

A. It -- it's more of a troubleshooting tool, if -- if they needed that information, but --
Q. Because it's the --
A. -- it's not --
Q. Because it's the difference between these --
A. Yeah. It's not a --
Q. -- products; right?
A. The -- it's useful for internal people to have access to that code.
Q. Because it's the differentiator between the products; right?
A. Because it's -- it -- it's used as part of the detection mechanism of the -- it's a handle that is used, so it's useful for them to know that.
Q. So the field reps -- excuse me.
The field-application scientists and the sales reps have the education or training to make use of this information about the oligonucleotide when they need to; is that accurate?
A. There's -- there was software available to the customer and to the sales rep that makes this

combination. They don't need to think about it.
Q. So there's a software that the customer uses to select which catalog code --
A. Yes.
Q. -- they would choose, and that has to be provided by Illumina to the customer?
A. Yes.
Q. And so when the customer wants to figure out what product to order, they go into the Illumina software and then figure it out there and then make their order?
A. The software is useful in the design of the assay that they're using these beads for.
Q. So before they ever make -- even make the decision to purchase, they're actually using software to design an assay?
A. No.
The decision to purchase is "I have a need for a multiplex assay, and I'm going to use these beads."
And the selection of the number of the beads is associated with how many analytes they

wanted to test.
When they received them and are trained to use them, there was software that managed this code of sequences.
Q. Are there a --
A. They don't think about that in the ordering process.
Q. Are there a ton of errors?
A. No, because they're software.
Q. So there's no errors?
A. I'm sorry?
MR. HORNE: Vague.
THE WITNESS: Um --
BY MR. HANKINSON:
Q. Do the customers make mistakes then have to trade out the orders because they got the wrong thing?
A. I've never experienced that happening.
Q. If you turn to the Frequently Asked Questions --
A. Uh-huh.
Q. -- at the -- in Exhibit 303, they start at

page 32.
A. Uh-huh.
Q. These are questions that were frequently asked by customers; right?
A. No.
The idea of a Frequently Asked Question was a tool that marketing provides to sales anticipating what -- what is the possible realm of questions that you might get asked, and trying to provide an answer.
It wasn't necessarily the other way around.
Q. It was anticipating what questions would be frequently asked?
A. Anticipating questions and providing an answer.
Q. "Frequently asked" is just a meaningless term here?
A. It's a --
Q. You weren't trying to anticipate --
A. It's kind of jargon, I guess is what I'm trying to say.

Q. But you --
A. The term "Frequently Asked Questions" is jargon.
Q. You weren't trying to anticipate every single question; you were trying to anticipate questions that would come up with a reasonable degree of frequency?
A. The -- the frequency is kind of arbitrary.
It's "Here's some canned answers for you, sales rep. I want to provide you answers that you might get asked."
Q. By the customer?
A. By a customer.
Q. Can you turn to page 34.
A. Uh-huh.
Q. The question -- this is the last one on page 34 is:
"What makes your product better than Luminex? They seem to be similar technologies."
Do you see that?
(Document reviewed by the witness.)

THE WITNESS: Yes, I do.
I'm sorry. I was reading it.
BY MR. HANKINSON:
Q. And that refers to the Illumina BeadXpress and the Luminex product that we were comparing in the table on page 5; right?
A. Yes.
Q. If you look at page 36 at the first question, it's:
"Can the BeadXpress Reader be used for diagnostic testing?"
Do you see that question?
A. Yes.
Q. The answer is:
"The BeadXpress Reader is currently labeled as a "Research use only" instrument, so it has not been reviewed by the FDA.
"But we have had a lot of interest expressed by CLIA high complexity certified labs who are interested in developing homebrew

assays with the technology."
Did I read it accurately?
A. Yes.
Q. So in the "Frequently Asked Questions" section of the training materials given to sales reps for the launch of the BeadXpress system and VeraCode technology in late 2008, it was anticipated that customers might ask whether the BeadXpress Reader can be used for diagnostic testing; right?
That's why this is here?
A. Yes.
Q. And the answer given to the sales reps, as you referred to as like the "canned answer," is that:
"While it's research use only, a CLIA high complexity certified lab could make an LDT."
And that would be the only thing the sales rep would be told about diagnostic testing using the BeadXpress Reader; right?
A. The answer that was provided was that a

CLIA high complexity lab that is interested in homebrew assays might be interested in the technology.
Q. There were no other customers listed in response to the question about whether the BeadXpress Reader could be used for diagnostic testing in this launch package; right?
A. I'm sorry? Could you restate the question?
Q. Yeah.
There's no other customers besides CLIA high complexity certified labs that are listed in the answer to this frequently asked question about whether the BeadXpress Reader could be used for diagnostic testing?
A. That's correct.
Q. Later on the same page, page 36 of Exhibit 303, the second question up from the bottom, within -- before the "Regulatory Terminology" heading, it asks:
"Can the GoldenGate genotyping assay be used for

diagnostic testing?"
Do you see that?
A. Yes.
Q. And there the answer is just:
"The GoldenGate genotyping assay is a research-use-only product. It has not been reviewed by the FDA."
Did I read that correctly?
A. Yes.
Q. So there are no diagnostic testing customers that could have made use of the GoldenGate genotyping assay for those purposes at that time; is that right?
MR. HORNE: Lacks foundation.
THE WITNESS: It -- no, it's not right.
BY MR. HANKINSON:
Q. The sales reps were told to respond that, "The GoldenGate genotyping assay is a research-use-only product"; right?
A. Yes.
Q. The next question down says:

"I work in a CLIA high complexity lab and would like to develop tests using the VeraCode technology.
"Will Illumina help me with designing and validating a test?"
Did I read that right?
A. Yes.
Q. When this question asks about developing tests using the VeraCode technology, is that referring to LDTs or homebrews?
A. Yes.
Q. And the implication here is that the LDTs or homebrews must be designed and validated, right, by someone?
A. Yes.
Q. And the question is:
"Will Illumina help with that?"
A. Yes.
Q. The answer is:

"No. Illumina can provide technical support for working with the VeraCode products and assist with troubleshooting, but the CLIA high complexity lab is responsible for designing and validating their own tests."
Did I read that right?
A. Yes.
Q. The technical support for working with the VeraCode products and the troubleshooting, those are not designing and validating the tests; right?
A. That is correct.
Q. Those are related to like customer service, troubleshooting issues if the machine's not working right; right?
A. That would certainly be covered, among other things.
Q. But none of the things involved with technical support and assisting with troubleshooting would be the design and validation of the test?
A. We did not assist a customer in designing

their test or validating their test.
Q. And you weren't permitted to; right?
A. That's correct.
Q. And why not?
A. Because they were not FDA approved.
Q. "They were not"?
Is that what you said?
A. I said "they."
Q. And who --
A. Well --
Q. -- are you referring to by "they"?
A. I'm sorry.
I was referring to the beads.
The product was not FDA approved or cleared.
Q. Can Illumina's IVD products be purchased and used by doctors in an office as opposed to a laboratory setting?
A. Can they?
Q. According to regulations.
A. No.
Q. Did you say "No"?

A. No. The answer's "No."
Q. So certainly they wouldn't be marketed to doctors sitting in offices as opposed to laboratories?
A. We would not do marketing to physicians for purchase of the technology; however, we do have marketing of our IVD tests to build awareness to an ordering physician.
They're not -- they're not the direct purchaser, but they're a -- a stakeholder in the process.
Q. The stakeholders who are involved in purchasing decisions for Illumina's products to be used in connection with clinical diagnostics include, as we had spoken about before, hospital administrators, which might be the president or someone very high up at the hospital, and it might also include a purchasing agent or purchasing department, the lab director, and the medical director; right?
A. I'm sorry? Can you ask the question again?

It was a -- a long question.
Q. It was. I'm just trying to get back to a topic.
A. Okay.
Q. So the stakeholders --
A. Uh-huh.
Q. -- that are involved in the purchasing decisions for Illumina's products for use in relation to clinical diagnostics --
A. Uh-huh.
Q. -- include lab directors, medical directors, and hospital administration; right?
A. All of those people could be involved.
Q. And the hospital administration can include someone as high up as the president of the hospital, and it can also include a purchasing agent or purchasing department at the hospital; right?
A. Yes.
In the event we're working on a large, committed, recurring revenue, oftentimes people high up in the organization would be involved.
Like a recurring test order -- a

commitment to a recurring test order would be -- may involve hospital administration.
Q. And if there's not a high volume of recurring revenue, then when you say that the hospital administration is involved as a stakeholder, it probably refers more to a purchasing agent?
A. That's right.
DEPOSITION OFFICER: Did you say "occurring" or "recurring"?
THE WITNESS: Recurring.
MR. HANKINSON: Recurring.
DEPOSITION OFFICER: I was asking him.
Thank you.
THE WITNESS: I'm sorry.
DEPOSITION OFFICER: Not you, him. It was what he said.
Thank you.
BY MR. HANKINSON:
Q. A lab director, in this context, would be someone with at least a Ph.D; right?
A. It's usually either a Ph.D or a

pathologist.
Q. A pathologist being a medical degree?
A. Uh-huh. Yes.
Q. A medical director, would that person normally have a medical degree?
A. Yes.
And that -- that's another example of a stakeholder that would be involved if it's a multi-year, high-volume commitment.
That's a -- usually not involved in the first purchase, but if we're making a big deal with a hospital for a multi-year commitment, then that person's usually involved.
Q. Uh-huh. Excuse me.
Yes.
A purchasing agent within the hospital would be someone whose job is to purchase products and to see that process through for many, many different products at the hospital.
Do I have that right?
A. I -- I don't know if they're responsible for multiple products or not, but from my experience

a purchasing agent places orders.
Q. So it could be the case that there's a person just responsible for one type of product purchase at the hospital?
A. I -- I just didn't -- you said many, many products. I -- I don't know what breadth of products every purchasing agent purchases, so...
Q. Their job is to buy things for the hospital?
A. Their job is to buy stuff, yeah.
Q. Does their job include either agreeing to or negotiating the price of the products?
A. It could be.
Q. Does their job include making sure that the hospital's purchase-order process is followed?
A. I don't know.
Q. What's your best understanding of what a purchasing agent does for a hospital in connection with products like Illumina's?
A. Placing purchase orders, ordering or reordering product.
Q. Did you have any sort of non-compete

agreement when you left Nanogen?
A. I don't remember.
Q. Did Illumina ever inquire whether anything would prevent you from working in the same industry as Nanogen?
A. I don't remember.
Q. Do you think you would remember if it had happened?
A. There was -- there was some sort of process when I was hired, and I think that question may have been asked, but I don't -- I don't remember exactly. It was a long time ago.
Q. 2007?
A. Yeah.
Q. Do you remember who you're thinking of that may have asked the question?
A. No.
Q. Just part of your on-boarding?
A. Yes. There's an on-boarding process at Illumina.
Q. I don't mean to like focus on it too much, but I'm just trying to figure out what the status

of "I think I remember that it might have been asked" is.
I mean, there's something that's prompting you not to just say, "No, it definitely wasn't asked."
A. I just kind of -- I just kind of remember it coming up. I -- I don't -- I don't remember exactly what the conversation was around non-compete.
There might have been something about Illumina.
I -- I just -- it was never an issue. I never had a non-compete conversation about Nanogen.
Q. In your declaration submitted in this case, at one point you discuss Illumina's attempt to position the BeadXpress platform to the molecular diagnostics market where Luminex Corp was a competitor.
So Luminex was in the molecular diagnostics field at the time?
A. Yes.

Q. And when Illumina wanted to position BeadXpress in that platform, it would in a sense become a competitor of Luminex by moving into that field?
Do I have that right?
A. Illumina -- I -- I don't know that I agree that the first intention to move into diagnostics had to do with the BeadXpress.
Q. Okay.
A. The -- the vision of the company was always to be a player in personalized medicine.
DEPOSITION OFFICER: "A player in..."?
THE WITNESS: "Personalized medicine."
DEPOSITION OFFICER: Thank you. I couldn't hear the last word.
BY MR. HANKINSON:
Q. Prior to your time in 2007, you're saying that that was the case?
A. I'm sorry? What's the question?
Q. Well, you said it had always been.
A. There was a --
Q. But you started in 2007, and the company

was founded in 1998, so I'm asking if you are referring to the time before you came or just after.
A. We were -- we just were talking about our vision statement as a company, and --
Q. Who was when?
A. My boss, John White, presented to my team Illumina's vision statement and how it has modified over the years. I mean --
Q. And when was that presentation?
A. This week.
Tracking over time, it showed that Illumina was interested in personalized medicine.
Q. Do you understand that there were corporation restructurings in 2008, 2011, and 2013?
A. Yes.
Q. And you're referring now to a presentation that was given to you last week characterizing what the company's vision had been in the past?
Is that what you're saying?
A. Yes.
Q. Did you take any steps to verify that the

characterization given in that presentation was true as of the times that were being characterized?
A. No.
Q. So we jumped off there because you took issue with whether my question was about a particular time related to BeadXpress or the company's vision.
A. Yeah.
Q. I'm going to quote from your declaration.
And -- I'm sorry. I didn't bring you a copy.
A. Okay.
Q. But paragraph 5 says:
"By that time" -- the first half of 2008 --
A. Okay.
Q. (READING):
-- "Illumina was positioning the BeadXpress platform to the molecular diagnostics market where Luminex Corp was a competitor."
A. Yes.

Q. So you're with me there?
A. Yes.
Q. And so BeadXpress, at the first half of 2008, was already an existing product; right?
A. Yes.
Q. It had been sold prior to that time; it wasn't like a new product that was about to launch?
A. Yes.
Q. But it had been a research-use-only product; right?
A. Yes.
Q. And it had been used in academic and other research environments up to that time; right?
A. The -- it had been used in research and academic environments and other environments as well.
Q. And in the first half of 2008, an environment that Illumina was positioning it for --
A. Uh-huh.
Q. -- forward going --
A. Yeah.

Q. -- was the molecular diagnostics market --
A. Yes.
Q. -- where Luminex Corp was a competitor; is that right?
A. Yes.
Q. Luminex, at that time, had molecular diagnostic tests for influenza; right?
A. Yes.
Q. And Luminex had a product named xMAP at that time; right?
A. Yes.
Q. And Illumina was -- and there's -- here's another quote from your declaration, paragraph 5:
A. Okay.
Q. (READING):
"Both Luminex's xMAP" -- MAP capitalized, "x" is little.
-- "and Illumina's BeadXpress could be used to detect variants in DNA in a multiplex fashion leveraging beads."
So as BeadXpress was positioned to enter

the molecular diagnostics market, a product of Luminex's that it would be competing with potentially was xMAP.

Do I have that right?

A. Yes.

Q. But in order to do that, the BeadXpress would have to be used in the context of an LDT because Illumina did not have, and was not planning to develop, an FDA cleared or approved assay; right?

MR. HORNE: Compound, lacks foundation.

THE WITNESS: I disagree that we did not intend to develop assays to be FDA cleared or approved.

BY MR. HANKINSON:

Q. But with respect to BeadXpress --

A. Uh-huh.

Q. -- that was not how BeadXpress was being positioned to enter the molecular diagnostics market at the time; right?

MR. HORNE: Vague.

THE WITNESS: Can you re-ask the question?

BY MR. HANKINSON:

Q. Yeah.

BeadXpress was a platform that could be positioned to be used by CLIA high complexity certified labs to create LDTs that then might test for things like influenza, potentially; right?

A. Yes.

Q. That was the intent in late 2008?

A. That was an -- an intent.

Q. BeadXpress was never going to be an assay; it was a platform on which assays could be run.

Right?

A. The BeadXpress was an instrument, and the consumables sold were -- made up the assay. We -- we offered consumables.

Q. Well, the consumables being sold were not assays?

A. We offered our GoldenGate assay and the --

Q. For research use only; right?

A. They're labeled as "For research use only."

Q. Okay.

A. That's right.

Q. And the BeadXpress -- the other -- you know, the consumables were not assays, right?

A. We offered our -- a methylation and a gene expression assay.

Q. Again, for research use only at the time?

A. Those were labeled "For research only."

MR. HORNE: Vague.

BY MR. HANKINSON:

Q. When you say that the consumables could be, you know, made into assays, that's through an LDT from a CLIA high complexity certified lab; right?

That's what you're referring to?

A. The -- to me, an assay is the assay process. That's why I'm confused with your question.

When you said --

Q. So you would agree that a consumable cannot be an assay, because one is a thing and another is a process?

A. Sometimes I've used the word "consumable"

in a -- in a synonymous -- synonymous way with our assays or our -- our products. So I would say some are packaged assays and some are components, when I say "consumable."

Q. And at the time, in the last half of 2008, if Illumina had been marketing its consumables as an assay for diagnostic purposes, it would have been in trouble; right?

That was a no-no?

MR. HORNE: Vague.

THE WITNESS: Can you ask me that question again?

BY MR. HANKINSON:

Q. Sure.

At the time, in the second half of 2008, if Illumina had been marketing its consumables as assays for diagnostic purposes, it would have been in trouble?

MR. HORNE: Same objection.

THE WITNESS: I don't know the answer to that question.

BY MR. HANKINSON:

Q. The FDA would not have approved of such a marketing practice for Illumina's consumables in the last half of 2008; correct?
MR. HORNE: Vague.
THE WITNESS: Um -- um --
BY MR. HANKINSON:
Q. Did you have an assay?
A. Uh-huh.
Q. Did Illumina have an assay in late 2008 that was cleared or approved by the FDA for diagnostic use?
A. We had our -- our universal and carboxyl beads that were registered with the FDA, and we could market those for -- as components for development of lab-developed tests.
And I --
Q. And your answer --
A. The date -- the date is not clear to me.
Q. Uh-huh. And they would only be components of a lab-developed test, not a complete assay; right?
A. Those are -- yeah, those are beads and

components that are part of an assay.
Q. And the assay would have been developed by the lab; that's why it's called an "LDT, lab-developed test"?
"Test" meaning assay; right?
A. I'm not sure that we're using the terminology consistency -- "assay, component, test" -- and that's why I'm struggling in answering your question.
Can you -- can you try to ask it again?
Q. Yes, I can.
When I asked you whether --
A. Uh-huh.
Q. -- Illumina was approved or cleared by the FDA to market assays --
A. Uh-huh.
Q. -- for diagnostics purposes, in my opinion you didn't answer my question.
A. Okay.
Q. And I'll explain why, and maybe that will explain why we're talking past each other.
A. Okay.

Q. Because your answer to that question was "We were selling certain components" -- and I think you listed carboxyl beads --
A. Uh-huh.
Q. -- and one other thing that could be used in developing an LDT.
A. Right.
Q. Right? That was your answer?
A. Oh, okay.
Q. Okay. So do you understand how we're communicating wrong?
A. So for terminology.
But the FDA will approve a test for specific intended use. And an assay, to me, is more of a -- a lab process that you're asking for detecting DNA or something.
And that's why I'm having a hard time answering your question.
Q. Oh.
A. It's because --
Q. Okay. Yeah.
A. -- of the use --

Q. Yeah. Yeah.
A. -- of the words --
Q. I'm sorry.
A. -- "assay" and "component" and "test."
Q. So at the time -- and I apologize.
So at the time in --
A. Uh-huh.
Q. -- 2008 Illumina would have been selling research-use-only assays and components for assays that might have been used by others in LDTs, but was not selling tests, and that's why we're having --
A. Yes.
Q. -- a disconnect?
A. Yes, that's correct.
Q. In 2008 Illumina wasn't selling tests?
A. That's correct.
Q. So when we discuss Exhibit 315 -- I'm sorry.
MR. HORNE: We've being going about an hour and a half so...
MR. HANKINSON: I think this is a short one.

MR. HORNE: All right.
(Whereupon, O'Grady Exhibit Number 315 was marked for identification by the Deposition Officer and is attached hereto.)
BY MR. HANKINSON:
Q. Take a look at what's been marked as Exhibit 315.
A. Uh-huh.
Q. Does this pertain to a grant from the Gates Foundation?
A. Yes.
Q. And the grant was made to the University of Maryland, and Illumina was going to, in a sense, partner with the University of Maryland on this grant; right?
A. We were a -- we were contracted by the University of Maryland to participate.
Q. And the University of Maryland was going to use Illumina technology to sequence diarrheal pathogens; right?
A. No, not correct.

It -- it was not a sequencing test.
Q. Okay. What does "Targeting signature sequences" mean?
A. The -- the technology that was used for this, the GoldenGate assay --
Q. Uh-huh.
A. -- would genotype or detect single bases and not sequence a string of bases.
So this was using our genotyping technology, not our sequencing technology.
It's a discrete change and not a series.
Q. And since this was GoldenGate, it was for research use; right?
A. The -- the label on the product was "For research use only."
Q. Uh-huh. And the purpose of the grant and the work by the University of Maryland was epidemiological; right?
A. Yes.
Q. Meaning sort of the tracking and tracing of the spread of disease?
Do I have that correct?

A. Yes.
Q. So the test to detect certain -- did you say "bases"?
A. Sure.
A nucleic acid base is the A's, T's, G's, and C's.
Q. Uh-huh. And so the test, the GoldenGate -- excuse me -- I shouldn't say "test."
The GoldenGate assay, which was targeting -- when it's signature sequences, that's where you're using the word "nucleic acid -- acid-based" -- something?
A. Yes.
Q. Okay. So the GoldenGate research-use-only assay was targeting those bases from particular pathogens to see which ones were occurring in which people specifically in order to, then, sort of map out the spread of disease?
Is that a fair statement?
A. The -- the assay was looking for -- the assay targeted sequences that corresponded to the infectious agents in the panel. There was 13 of

them.
So it was looking for those pathogens in -- in humans.
Q. And those humans were not patients that were being diagnosed and treated, were they?
A. I'm not aware if they were being diagnosed or treated.
Q. Well, they weren't being diagnosed or treated through the work of the University of Maryland; right?
A. I don't know whether they were or not.
Q. The GoldenGate assay wasn't being used to diagnose or treat anybody; right?
A. I don't know if the University of Maryland used the GoldenGate assay to diagnose or treat patients.
Q. You're not asserting that in your declaration?
A. I'm sorry?
Q. You are not asserting that they were in your declaration, are you?
A. I -- I don't think I did that, no.

Q. Because you don't know?
A. I don't know if they did that or not.
Q. The University Maryland was a research institution; right?
MR. HORNE: Vague.
THE WITNESS: I -- I don't know.
///
BY MR. HANKINSON:
Q. Exhibit 315 was non-public; correct?
A. It's -- that's correct.
Q. In fact, it's labeled "Trade Secret/Commercially Sensitive" here.
A. The presen- -- this looks like it was something that was added. They're -- I don't know the right terminology.
Q. Yes, that's correct.
A. The presentation itself, and then this part below it --
Q. Uh-huh.
A. -- that -- that part below it was something that was added in the pdf.
Q. Do you disagree that it was either a trade

secret or commercially sensitive information?
A. No, I don't disagree.
Q. Okay.
A. I'm -- I'm just saying that the presentation and -- and this (indicating) -- like, we labeled -- I guess --
Q. But you agree --
A. -- the lawyers --
Q. -- with the label?
A. -- labeled that.
Q. Yeah.
A. I agree with it, yeah.
Q. You agree with the label?
A. Yeah.
MR. HANKINSON: We can take a break.
DEPOSITION OFFICER: Off the record.
(Whereupon, a recess was held from 11:18 a.m. to 11:39 a.m.)
DEPOSITION OFFICER: Back on the record.
BY MR. HANKINSON:
Q. I'd like to hand you what we are marking as Exhibit 302.

(Whereupon, O'Grady Exhibit Number 302 was marked for identification by the Deposition Officer and is attached hereto.)
DEPOSITION OFFICER: There you go.
THE WITNESS: Thank you.
(Document reviewed by the witness.)
BY MR. HANKINSON:
Q. Is this a presentation given by Ms. Henshall in 2007?
A. Yes.
(Interruption in proceedings.)
///
BY MR. HANKINSON:
Q. Could you just turn to the last page.
A. Is this what you want me to look at?
Q. Yeah.
A. Okay.
Q. Is this part of the presentation?
(Document reviewed by the witness.)
THE WITNESS: This -- I'm just looking through the series of slides really quick.

This presentation was given many times in different formats. It's like a standard story.
And it looks like in this instance it was given before we had a speaker talking about the use of the technology for different applications, so this was like an introductory slide to that person's story.
BY MR. HANKINSON:
Q. Was that person Leslie Lyons?
A. Yes.
Q. Is that a guy or a girl?
A. That's a woman.
Q. Was she affiliated with Illumina at the time, or was she independently employed at the Department of Population Health and Reproduction School of Veterinary Medicine, University of California Davis?
A. She was not affiliated with Illumina.
Q. I'd like to turn your attention to Exhibit 304, which we will mark.
(Whereupon, O'Grady Exhibit Number 304 was marked for identification by

the Deposition Officer and is attached hereto.)
THE WITNESS: Thank you.
DEPOSITION OFFICER: Uh-huh.
BY MR. HANKINSON:
Q. Is Exhibit 304 the "Diagnostics Portfolio Management Plan" from July 20th, 2009?
A. Yes.
Q. Illumina first began making formal annual portfolio plans to assess potential business development options in 2009; right?
A. That's right.
Q. So this is the first document of its kind for diagnostics portfolio management?
A. I'm -- I'm not aware if there were informal plans prior to 2009, but this is the first in this corporate planning process.
Q. Are all of the people who are listed on the first page of the Diagnostics Portfolio Management Plan co-authors?
A. They all were on that team that developed the document.

Q. Did they all have sign-off on this document?
A. There wasn't an official sign-off; it was -- they were more authors.
(Interruption in proceedings.)
BY MR. HANKINSON:
Q. So they all had input into this document?
A. They all had input, yeah.
Q. Did you have any input into this document?
A. I assisted Mickie.
Q. Were you aware of the full contents of the document before it was finalized?
A. I -- I'm trying to think. I'm not sure if I -- I think so, yes.
Q. Would you have brought it to the attention of the -- of Ms. Henshall or another author of this document if you were aware of any inaccuracy in it?
A. If I saw an error, I would have raised it, yes.

Q. Who was the intended audience of this document?
A. Senior management.
Q. Who would that include?
A. In 2009 I'm not certain who the -- I don't remember the exact --
Q. By position.
A. -- makeup --
Q. By position.
A. -- but the -- the CEO.
Q. And others in senior management?
A. And others in senior management, yeah.
Q. This went all the way to the top of the company?
A. Yes.
Q. So it was important to the authors' jobs and departments that the information in this would be completely accurate so that the senior management could make decisions based on it; right?
A. Yes.
Q. When Illumina offers a new product, does the decision whether or not to do so always go to

the board of Illumina?
A. No.
Q. When Illumina decides to begin developing a new product or service, does that decision always go to the board of Illumina?
A. No.
Q. Those are business decisions that can be made by management; right?
A. Yes.
Q. Could you turn to page 3 of Exhibit 304.
I'd like to direct your attention to the third sentence of the paragraph in the middle of the page. It says:
"Without leveraging an acquisition strategy, comparable companies have typically shown of span of eight to ten years before establishing a successful business in molecular diagnostics."
Did I read that right?
(Document reviewed by the witness.)
THE WITNESS: Yes.

BY MR. HANKINSON:
Q. This refers to essentially the lead time of companies comparable to Illumina who wanted to establish a molecular diagnostics business, from the time that they wanted to be into it until the time that they had a successful business in it.
Is that accurate?
A. Yes.
Q. And the implication is that by leveraging an acquisition strategy, maybe that could go faster; is that right?
A. Yes.
Q. And then if you go down to "Pipeline Overview," the first sentence is:
"The diagnostic product development pipeline can be divided into three main sections: (1), cancer biomarker discovery; (2), molecular diagnostics panels; and (3), clinical sequencing service."
Is that accurate?

A. Yes.
Q. Is this a forward-looking statement about development of future diagnostic products and services?
A. Yes.
Q. Could you turn to page 7.
Looking under "Competitive Advantage" -- and this is the section related, "Molecular Oncology."
A. Okay.
Q. Do you agree with that?
(Document reviewed by the witness.)
THE WITNESS: Yes.
BY MR. HANKINSON:
Q. And was oncology your role at the time?
A. Yes. I covered oncology as well as genetics applications at that time.
Q. Under the section "Competitive Advantage," the first sentence states:
""With a discovery program that is focused on comprehensive genetic analysis, including whole

transcriptome and methylome analysis" --
Those both end in "o-m-e."
"-- Illumina has a potential to develop a highly specific diagnostic test that addresses the complexities inherent in cancer."
Do you see that?
A. Yes.
Q. "Potential to develop" means that Illumina did not have a test at that time; right?
A. That's correct.
Q. And that test, if and when it was developed --
DEPOSITION OFFICER: I couldn't hear the last few words you said.
BY MR. HANKINSON:
Q. -- would deal with human DNA; right?
A. Yes, that's correct.
Q. So when you called this a diagnostic test -- excuse me. Let me ask a different question.

The last sentence in this paragraph reads:
"Relative to earlier cancer diagnostics in the market, Illumina shall have a rapid path to commercialization through an initial offering as a service by the CLIA lab, which shall facilitate data generation for a likely PMA submission to the FDA."
Do you see that?
A. Yes.
Q. So in July of 2009, the steps to develop a diagnostic test that addresses the complexities inherent in cancer would include first developing and then offering a service by Illumina's CLIA lab, which would then facilitate data generation; meaning, lead to increased data in that field that would then, after that, be used in a likely PMA submission to the FDA.
Do I have that right, that those are sort of steps to the commercialization of such a

potential product?
A. That -- that was the plan for this discovery initiative.
Q. Can you turn to page 12.
And perhaps utilizing the prior couple of pages, could you confirm that the key dependencies on page 12 relate to the potential development of products around a "herpes panel" or "viral infections in transplant panel"?
A. I'm sorry. I was referring to the previous pages when you said that.
Can you ask me the question again?
Q. Sure.
Do the key dependencies on page 12 have to do with the potential development of what might be called a "herpes panel" or "viral infections in transplant panel"?
A. The --
Q. You might refer to page 10.
A. Okay.
(Document reviewed by the witness.)
THE WITNESS: The -- the forecast

projections that are defined on page 12 are dependent -- the key dependencies are in reference to the forecast projections on page 12.
BY MR. HANKINSON:
Q. And all of that relates to the herpes panel; correct?
A. If I can review this for a second, please.
(Document reviewed by the witness.)
BY MR. HANKINSON:
Q. I should say "the development of a potential herpes panel."
A. I'm not -- I'm not clear by looking at this right now if that revenue is representative of herpes or hospital-acquired infections -- and/or.
So I'm -- I'm not -- I'm not super sure.
Q. It looks to me like there are main headings like "Cancer Biomarker Discovery Program," "Pharmacogenomics - ADME Core & CYP2C19," and "Herpes Panel," each of which is followed by a "Market Summary," a "Competitive Advantage," a "Forecast," and "Key Dependencies" in this document.
A. Uh-huh.

Q. And then on page 10, it starts a "Herpes Panel" or "Viral Infections in Transplant Panel" section.
A. Okay.
Q. It is then followed a by a "Market Summary," a "Competitive Advantage," a "Forecast," and "Key Dependencies."
Does that help to answer whether these forecasts and key dependencies relate to a herpes panel?
A. Yes, those refer to the herpes panel.
Q. And the herpes panel at the time was a potential product development, not a current product; right?
A. This was a plan for future products.
Q. One of the key dependencies on page 12 is to:
"Complete EraGen/Illumina agreement; enable development with EraCode modified bases."
Do you see that?
A. Uh-huh.

Q. Was that agreement completed?
A. Yes.
Q. Subsequent to the agreement being put in place, was EraGen purchased by Luminex?
A. Yes.
Q. And Luminex is a competitor of Illumina's?
A. Yes.
Q. Was there any impact of the purchase of EraGen by Luminex on the ability or intention of Illumina to develop this product?
A. I'm not aware of what happened in the relationship after the acquisition of Luminex.
Q. But the product hasn't been developed?
A. No, the product hasn't been developed.
Q. And, in fact, it says later on in this bullet, "...the Dx platform team believes that Illumina's infectious disease assays will need to be reconsidered..." if EraGen's rapid assay chemistry is not available to Illumina.
Do I have that right?
A. It says that the "FastGoldenGate assay"

would not be competitive.
Q. So the potential development of the herpes panel might need to be reconsidered if EraGen's technology was not available?
A. That's what it says.
Q. Do you have any reason to disagree with it now?
A. No.
Q. It also says that a key dependency is:
"R&D developers experienced in designing assays with viral targets."
Did I read that right?
A. Yes.
Q. So in forecasting potential revenue from a potentially developed herpes panel, one thing that that project and those revenues would depend on was hiring or acquiring R&D developers who were experienced in making assays with viral targets such as herpes?
A. That -- that's not exactly what it says.
It says that a dependency is:

"R&D developers experienced in designing assays with viral targets."
It doesn't talk about a hiring plan.
Q. Right.
I'm trying to picture a scenario in which Illumina would have had R&D developers experienced in designing assays with viral targets already, and yet listed it on a key dependency list.
So doesn't that mean that they weren't in place at that time?
A. It does not mean that they weren't in place at that time.
Q. But they weren't, were they?
A. We had a team working on the application of the GoldenGate assay for a infectious diarrhea panel for the University of Maryland relationship.
There were R&D developers experienced in viral targets.
The point of that bullet was to identify that we needed specific resources applied to this project, not just any R&D team.

Q. And that was not in place at the time?
MR. HORNE: Lacks foundation.
BY MR. HANKINSON:
Q. What you just described was not in place already?
A. The -- the point of the document --
MR. HORNE: Vague.
THE WITNESS: -- is to ask for a new project that we want to do, so we were saying we want -- we want these resources in order to do that project.
BY MR. HANKINSON:
Q. Could you turn to page 15.
The heading at the top is "iScanDx for Cytogenetics"; right?
A. Yes.
Q. And does that begin a section related to a potential cytogenetics diagnostic product?
A. Yes.
Q. I'd like you to turn to the next page where the key dependencies for that cytogenetics potential diagnostic product are listed.

Do you see that?
A. Yes.
Q. In the fourth bullet, it says:
"Document remediation to bring the iScan instrument under design control, or creation of a new scanner under design control."
Did I read that right?
A. Yes.
Q. So in July 2009, there was such a thing as an iScan instrument that already existed in the world; right?
A. Yes.
Q. And was that a product that was being sold at the time?
A. Yes.
Q. Was it a research-use-only product?
A. The instrument was labeled "For research use only."
Q. It's interesting, whenever I ask if it was research use only, you say "The instrument was labeled for research only -- the instrument was

so it's speculation. It takes time to get a product FDA cleared.

Q. It's speculation what would have happened in the future. But at the time, it's not speculation to say what the plan was?

A. There wasn't -- there wasn't a specific branding plan with any of these products. Our umbrella brand at that time was Illumina Dx.

Q. But you said you didn't know when Illumina Dx began to be the brand.

A. Yeah, that's true.

If -- there wasn't a specific branding strategy involved in this document.

Q. As of July 2009 --

A. Um --

Q. -- which is the date of this document?

A. In -- in this document we did not talk about what the brand would be for the respiratory viral panel.

Q. Okay. But I've been asking you what the plan was at the time.

A. I don't know.

in a separate team that was product marketing.

Q. Sorry. I guess that's a midwestern term.

You're in a dynamic team with many touch points like neurons.

A. I was in a cross-functional team that interfaced with brand.

Q. That's wonderful.

A. That was product marketing.

Q. So it circled back.

You don't know what, if any, plan existed as of July 2009 for the branding of any of the products that are contemplated as future-developed products in Exhibit 304?

A. We --

Q. I thought you just told me you don't?

A. This -- this prod- -- I'm -- I'm trying to explain -- okay. No.

The answer to your question is "No."

Q. If you look at page 20, at the bottom there's another reference to Luminex, this time in the context of "respiratory viral"; is that right?

A. Yes.

Q. You were working in part as a member of a team to develop products for the molecular diagnostic market in oncology; right?

A. Yes.

I'm sorry.

Q. No worries.

A. Yes. I nodded.

Q. Would you in that role have been aware of the branding plans as they existed at that time?

A. Product marketing and brand were separate organizations -- separate teams, so I don't know what their opinion was at that time of our brand planned for these products.

Q. Is Karen Possemato a member of the product branding team?

A. Are you asking me if she is today?

Q. At any point in time.

A. Karen Possemato led our corporate marketing organization, which included brand.

Q. And you were in a different silo, which was product marketing?

A. I don't agree that it was a silo. I was

Q. And the Luminex product there was xTAG; is that right?

A. Yes.

Q. So had Illumina's RVP panel been developed, it would have been in competition with Luminex xTAG?

A. Yes.

Q. Could you turn to page 21.

Here we see the key dependencies for the respiratory viral panel; right?

A. Yes.

Q. And then in the fourth bullet of those key dependencies, it says:

"Performance meets or exceeds performance demonstrated by Luminex RVP as predicate device for FDA submission."

Did I read that correctly?

A. Yes.

Q. So I think this might shed light on the sentence we were discussing on page 18 that you said didn't make sense. And let's examine that.

So the second sentence under "Respiratory Viral Panel" on page 18 says:

"To compete against the Luminex RVP panel and leverage its 510(k) clearance, Illumina's panel shall be comprised of a 14-plex (plus two internal controls) assay targeting the viruses and bacteria listed below."

Right?

A. Yes.

Q. So when we see in the key dependencies on page 21 that Illumina, at the time, was considering relying on the Luminex RVP as a predicate device for its FDA submission, then that makes sense, right, that it would be leveraging the prior FDA 510(k) clearance of the Luminex RVP panel; right?

A. It's assuming we would be allowed to use that as a method of comparison to our own device.

Q. This plan is assuming that?

A. This plan is assuming that if we were to

develop our own test, that we could use the Luminex RVP panel as a method of comparison.

Q. And to use a device as a predicate device in a 510(k) clearance, it would have to be in the same field doing the same function and at least as safe and effective or more; right?

A. No.

Q. Well, what are the requirements for listing a predicate device in an FDA submission?

A. It's the specific sensitivity and specificity claims. It -- it's saying that we would compare ourselves to those -- those claims.

Q. For doing the same thing?

A. For doing the same thing.

Q. And that expedites FDA clearance if you can show that; right?

A. It doesn't necessarily expedite FDA clearance.

Q. Is the reason for listing a predicate device to try to expedite FDA clearance?

A. It's -- no.

Q. What is the reason to even try, then?

A. As part of a 510(k), the performance of the test has to be compared to something, and usually that's assaying or sequencing.

And in this case, they were assuming they would be able to compare themselves to the Luminex system instead of assaying or sequencing.

Q. So had an RVP panel been developed, it would have done the same thing as Luminex RVP, and the plan was that Illumina could show in a 510(k) application that its sensitivity and -- what was the other word?

A. Specificity.

Q. -- specificity were as good or better than Luminex's RVP?

A. Yes.

Q. I'd like you to turn to page 22 where the heading is "BeadXpress II."

Under the heading "Market Summary" in the last sentence, it states:

"The clinical market is not funded for capital equipment purchases, so the instrument

systems are a function of reagent rental contracts, rolled into the overall price per test (or placed at no charge in some instances)."

Is that correct?

A. Yes.

Q. The clinical market is the market in which Illumina's contemplated potential diagnostic products would be sold; right?

MR. HORNE: Vague.

THE WITNESS: Can you restate the question?

BY MR. HANKINSON:

Q. Yes.

The clinical market, as used in the sentence that is the last sentence under "Market Summary" on page 22 of Exhibit 304, is the market into which Illumina's contemplated potential molecular diagnostics products would be sold?

MR. HORNE: One more objection.

Vague, lacks foundation.

BY MR. HANKINSON:

Q. Is that correct?
A. The -- the tests that were described in this plan were intended to be sold in the clinical market.
Q. No such test existed in July 2009; correct?
A. It's possible that some of the items described in this plan were available as -- were available or under development.
It's not necessarily true that none of them existed.
Q. None were being sold at the time; correct?
A. I'm not -- I'm not sure.
Q. You don't know one way or the other?
A. I don't know -- I don't know one way or the other.
Q. Before July 2009, had Illumina ever given a platform to a clinic or a lab for free?
A. I don't know of specifics around instrument giveaways.
Q. You just don't know one way or the --

however, development will need to be initiated and resourced by Q2 2011."
Right?
A. Yes.
Q. In July of 2009, Illumina R&D was selling a Prometheus product; is that correct -- pardon.
Illumina was selling a research-use-only-labeled Avantome sequencing system that was also known as "Prometheus"; is that right?
A. No.
Q. It wasn't selling it?
A. No.
Q. Was it a product in development?
A. I'm not sure.
Q. Do you know anything about it?
A. A little.
Q. What do you know?
A. You know, I'm not -- I'm not sure about the specifics about Avantome.
I -- I'm concerned that I'm confused about

A. I just --
Q. -- other?
A. -- don't know.
Q. Could you turn to page 23.
A. Sure.
Q. The heading that starts a little bit down on the page is "Diagnostic Targeted Sequencing (Prometheus II)"; right?
A. Yes.
Q. Does this relate to sequencing technology?
A. Yes.
Q. Could you look at "Forecast Projections" on page 24.
Are you with me?
A. Oh. I see, yes.
Q. There it states:
"Based on the development times for a major system developed under regulatory design control, we do not anticipate commercialization until 2013;

a different technology. But I think it involved a relationship with another organization. I'm not -- I'm not really sure.
Q. Thank you for clarifying. I appreciate it.
Under "Forecast Projections," the reference to "development times for a major system developed under regulatory design control," was that the same design control that we were discussing earlier for FDA submissions?
A. Yes.
Q. And the idea here is that to develop the Prometheus II diagnostic target sequencing, from the beginning it would be intended to be developed under regulatory design control so that when it was designed and developed, that design control could be used in support of an FDA submission; is that right?
A. Yes.
Q. So for this one, where the design of the product Prometheus II was being contemplated from scratch, essentially, the plan was, under "Key

Dependencies," that the project be "resourced and scoped to require regulatory design control" right from the beginning; right?

A. You said a lot of stuff in that sentence.

Can you maybe start over so I can make sure I'm understanding what I'm agreeing to?

Q. Sure.

For this one -- are you comfortable reading stuff back?

DEPOSITION OFFICER: Sure. I'll do my best.

MR. HANKINSON: Let's try that.

(THE RECORD WAS READ AS FOLLOWS:

Q. So for this one, where the design of the product Prometheus II was being contemplated from scratch, essentially, the plan was, under "Key Dependencies," that the project be "resourced and scoped to require regulatory design control" right from the beginning; right?)

THE WITNESS: I -- I -- okay. Hold on.

(Document reviewed by the witness.)

THE WITNESS: Does -- did the question say "Prometheus" or "Prometheus II"?

DEPOSITION OFFICER: "Prometheus II."

THE WITNESS: Yes. The answer is "Yes."

BY MR. HANKINSON:

Q. If you turn to page 26, there's a list of CLIA labs certified to perform transplant testing; correct?

A. Yes.

Q. If you look at the fourth one up from the bottom, it's "Beth Israel Deaconess Medical Center."

Do you see that?

A. Yes.

Q. Do you know if that's in Boston?

A. I don't know.

Q. Could you turn to page 29 of Exhibit 304.

Near the top of page 29, there's a major heading that says "Development Costs."

Do you see that?

A. Yes.

Q. This is a heading that is general; right? It's not specific to one of the particular potential diagnostic products that we've been discussing under the other headings?

A. Yes.

Q. And so this is the development cost section that applies to the entirety of the July 20th, 2009, Diagnostics Portfolio Management Plan; right?

A. Yes.

Q. The full text under Development Costs is in brackets, centered on the page, and it says:

"Still in process. Mike to provide soon."

Do I have that right?

A. Yes.

Q. Who is "Mike"?

A. I'm not sure.

Q. The next major section is titled "Internal Dependencies"; right?

A. Can I -- can I go back to your last

question you asked about Mike?

Q. No.

A. Okay.

Q. Yes, you may.

A. I was confused because there was more than one Mike, but the author was Mike Poirier, finance team member. That's who it was coming from.

Q. So the Mike mentioned on page 29 is an author of the Diagnostic Portfolio Management Plan, that is Exhibit 304, but at the time that it was created, did not provide the development costs to fill into this section?

A. That's right.

Q. So the next major heading is "Internal Dependencies"; right?

A. Yes.

Q. And there's a chart that lists "Short-term Needs," "Mid-term Needs," and "Long-term Needs," in three different columns; right?

A. Yes.

Q. And on that page and the pages that follow, there are rows listing the short-term,

mid-term, and long-term needs for: Instrumentation, Automation, Assay/Technology, Manufacturing, Software/Analysis, Regulatory -- excuse me -- Regulatory/Quality/Legal, Field Service & Support, Sales Channel, Marketing, Other, and CLIA Services.
Right?
A. Yes.
Q. On page 30 in the row that pertains to the short-term, mid-term and long-term needs for Assay/Technology, in the column listing short-term needs, the third bullet point reads:
"Less expensive, less complex workflow."
Do you see that?
A. Yes.
Q. What is meant by "less expensive, less complex workflow" here?
A. I'm not sure exactly which application that's referring to.
Q. It might refer to one or more of the potential diagnostic products referenced throughout the plan, and you're not sure which one or more?

A. Yes.
Q. In the row pertaining to "Manufacturing," in the column pertaining to mid-term needs, in the last bullet, it reads:
"QSR compliant manufacturing for iScan and select BeadArray and Avantome products for Dx."
Do you see that?
A. Yes.
Q. What is "QSR compliant"?
A. It's in reference to a manufacturing process. "Quality System Regulations" is what it stands for.
Q. What is the source of the Quality System Regulations?
A. It's FDA.
Q. Does this relate to the design control references in the dependencies that we spoke about earlier within this document, Exhibit 304?
A. Yes, that is part of the Quality System Regulations.
Q. So a mid-term need for Illumina to

realize the diagnostics plan that's set forth in Exhibit 304 is to have QSR compliant manufacturing, otherwise known as, you know, "bringing the product development under design control" -- as it's referenced elsewhere in the document -- for iScan and select BeadArray and Avantome products?
Am I summarizing that correctly?
A. The design control part and the manufacturing part are distinct; they both fall -- fall under QSR.
Q. Oh, interesting.
A. And they're both required.
Q. So in an FDA submission to get clearance or approval for a diagnostic product, there's two parts of QSR that would need to be addressed as to the product that's being submitted, one being design control and one being the manufacturing process?
A. Both -- yes, both of those are requirements for a submission.
And design control covers manufacturing as well as the upstream development of a product.
QSR and design control aren't synonyms, is

what --
Q. It's a rhombus --
A. -- trying to correct you on.
Q. It's a rhombus and a square.
So design control includes both manufacturing and the development of the product, whereas QSR compliant manufacturing would just be what you referred to as upstream?
A. Another term that's been used is "GMP," or Good Manufacturing Processes.
Q. And why do you bring that up?
A. Because the name has changed over time.
There's a manufacturing component and there's the development component, and both of those fall under QSR.
Q. So --
A. The terminology is a bit confusing.
Q. In July of 2009, to market an FDA cleared or approved product that was iScan, BeadArray, or certain -- certain BeadArray and Avantome products, there was a need to change the manufacturing that Illumina was doing to make it QSR compliant for the

FDA submission.
Is that accurate?
A. No.
Q. Okay. Please explain.
A. Well, we talked about the development of an Avantome product from scratch, so there wasn't a need to change manufacturing; it needed to be developed following QSR.
Q. Oh. Interesting.
Okay. So that's Avantome.
A. The --
Q. Whereas iScan -- you were taking issue because I said "change"?
A. Yeah.
Q. And iScan would be a change, whereas Avantome would be starting from scratch?
A. Right.
Yes, Quality System Regulation compliant manufacturing would be need to be developed for iScan and BeadArray as well, or the -- or the process modified.
I -- I don't know exactly how they would

go around making that change.
Q. On page 31 in the row related to "Regulatory/Quality/Legal," and the column related to short-term needs, the second bullet is:
"In-house regulatory expert."
Do you see that?
A. Uh-huh.
Q. As of July 2009, did Illumina have an in-house regulatory expert, or was one needed, as stated here?
A. I don't know when our internal regulatory organization started. I -- I don't -- I'm not sure.
Q. And it does not refresh your recollection that this is referred to as a "short-term need"?
A. No.
Q. You just don't know one way or the other?
A. I -- I don't know when our internal regulatory organization was established.
Q. Did it happen after you began working at Illumina in 2007?

A. Yes.
Q. Do you know if it happened in your first year with the company in 2007?
A. I -- I don't remember. I don't remember who had that responsibility.
Q. If Illumina had in-house as of July 20th, 2009, an in-house regulatory expert, would you expect that that person, or someone from their department, would be a team member in authoring the "Diagnostics Portfolio Management Plan"?
A. Not necessarily. This is more about business opportunity.
Q. There is a member of marketing, a member of finance, a sustaining team member, a production team member.
"Production" would be manufacturing; is that right?
A. Uh-huh.
Q. A development team member. Would that be like research and development?
A. It just -- it just says "development."
Q. Yes. And I'm asking you whether that

refers to research and development or some other sort of development.
A. It's product development.
Q. Product development.
And then also Dx development team member; right?
A. Our executive advisor, Greg Heath, came to the company with substantial amount of IVD experience and provided the guidance as to which directions we should be going in the diagnostics market.
Q. When did he begin his employment at Illumina?
A. It was after I joined the company; I don't remember exactly what year.
Q. And since Greg Heath, the executive advisor, was providing input into which direction Illumina should go with respect to diagnostics and regulatory matters at the time, according to what you just said, and he is an author on this plan, do you think he would put "in-house regulatory expert" as a short-term need if that had already been

fulfilled?
A. I -- I -- I don't know exactly what they were asking for there.
Q. It says "in-house regulatory expert."
A. I -- I know that.
But I'm not sure if they're asking for more resources for particular projects, or if there was someone already in the company.
There -- there are people that this -- with this responsibility, and I don't remember when they started and if it was before this was written.
That's why I'm not answering you directly, because I don't remember.
Q. So you agree that you're not answering me directly? Objection.
And I'm just going to keep on this a little bit --
A. Okay.
Q. -- and we'll see if we get anywhere.
So I'm viewing authors.
A. Uh-huh.
Q. And you -- when I asked whether you would

expect a regulatory team member to be an author, if one existed, you said -- you didn't say "Yes" or "No," if I'm remembering correctly -- you said, this is a like -- you said "finance" or like "business plan."
And then I'm seeing people who are like manufacturing, so it's certainly not just finance and strategy people; it's people giving input about, you know, what it's going to take.
This is why I'm asking the question. I'm trying to explain it to you --
A. Uh-huh.
Q. -- so that we're communicating.
And so does that -- and so let me ask: Given that this variety of people were involved in authoring this plan, now being cognizant of that, would you expect that if there was an in-house regulatory expert or a team, that a member of that team would be an author on this plan?
A. You said that manufacturing was on the team, and --
Q. It says "production," and I'd asked you if

that meant manufacturing. I thought you had said "Yes."
A. Okay. Okay. I don't disagree with that.
Can you ask me your question again?
You're asking me if -- if there was someone on regulatory on the team?
Q. If a person was in place in-house who was a regulatory expert, or a team of such people, would you expect a member of that team to have been an author on this?
A. Not necessarily.
Q. If you look at page 32, it carries over from the prior page the row dedicated to "Regulatory/Quality/Legal" needs.
In the second-to-last bullet --
A. Uh-huh.
Q. -- it states:
"Chief medical officer (for Safety Board and Reimbursement Program)."
A. Yes.
Q. What is the "Safety Board and

Reimbursement Program"?
A. I do not know what is meant by "Safety Board."
"Reimbursement" is in regards to how clinical laboratories get paid for diagnostic tests.
Q. Did Illumina have, in July 2009, a chief medical officer?
A. I am not aware of when our chief medical officer started.
Q. Do you think that it's conceivable that this bullet point saying chief medical officer --
A. Yeah.
Q. -- is a short-term need --
A. Yeah.
Q. -- that that would refer to just retaining the current chief medical officer?
A. The -- at the time this was written, the team was emerging, and exactly the series of events, I'm not clear on.
Around this time frame we got a chief medical officer. I don't know exactly when. He may

or may not have been here when -- at the time this was finally published.
Q. At or near July 2009, Illumina hired a chief medical officer?
A. We recognized the need and brought someone into the organization. I don't know exactly when he started.
Q. What was wrong with "hired"?
You -- are you saying that you --
A. It's just --
Q. -- recognized --
A. -- a process.
Q. -- the need in July 2009 and brought them in later?
A. It's -- it's -- the creation of these documents is a process.
Q. Is this the final one?
A. I believe so.
Q. And it's dated July 20th, 2009; right?
A. It is dated July 20, 2009.
Q. So at that time, at least the need for a chief medical officer had been identified?

A. Yes.
Q. And that need was related to moving into marketing of reimbursed diagnostic products; right?
A. Yes.
Q. And then sometime at that time or after, a chief medical officer was brought into the organization?
A. Yes.
Q. If you look at the next bullet, there's "Intensive Regulatory Training for Key Area Managers."
Do you see that?
A. Yes.
Q. And that is a short-term need related to the plan that is Exhibit 304; right?
A. Yes.
Q. At that time, had Illumina already given intensive regulatory training to the key area managers?
A. There were a few people at the company with that experience.

Q. Had Illumina given --
DEPOSITION OFFICER: "Given..."? --
BY MR. HANKINSON:
Q. -- given them that experience or trained them?
A. I don't know.
Q. In any event, their experience is not what's being referred to by "intensive regulatory training for key area managers"; correct?
A. Correct.
Q. That was something separate that was needed in the short-term; right?
A. Yes.
Q. If you look in the next row, "Field Service & Support," a mid-term need, in the middle column at the second bullet was:
"Designated Dx field support team for clinical customers (FAS, FSE, and Tech support)."
Right?
A. Yes.
Q. What is "FAS"?

A. It's either "Field Application Specialist" or "Scientist." I'm not -- I'm not sure on the "S".
Q. In any event, it's someone who is scientifically trained?
A. It's a person that offers on-site support and consulting to a customer.
Q. Are they scientifically trained?
A. Yes.
Q. And what is "FSE"?
A. A "Field Service Engineer."
Q. And what is that?
A. It's an individual that services equipment.
Q. In July of 2009, did Illumina have an existing field support team?
A. Yes.
Q. The need identified in the second bullet that we were discussing is to designate a field support team specifically for clinical customers; is that right?
A. Yes.
Q. If we look in the next row, "Sales

Channel," the top bullet of the mid-term need is:

"Separate diagnostic sales team focused on sales of Illumina's diagnostic portfolio exclusively."

Is that right?

A. Yes.

Q. In July 2009, did Illumina have a sales team already?

A. Yes.

Q. And the mid-term need that was being listed in this plan was to specifically devote a sales team to the diagnostic field; right?

A. Yes.

I -- I would say maybe not "specifically devote," but segregate. There were individuals that were accountable for that market.

Q. And by "individuals that were accountable for that market," are you referring to individuals that sold products labeled "research use only" into CLIA high complexity certified labs?

A. That, as well as our FDA registered

Universal Capture and Carboxyl Beads.

Q. Which were under a -- did you call it a Level I?

A. Class I exemption.

Q. "Class I exemption," meaning they were exempt from the FDA -- what are they exempt from?

A. It's a -- it's a level of safety and risk.

The -- the exact meaning of that is something you'd have to get some regulatory expert to comment on.

Q. And they're a --

A. I don't want to speculate.

Q. And they're a component, not a test?

A. They're a component.

Q. In the row related to "Marketing" lower down on page 32 of Exhibit 304, the first bullet is:

"Development of Illumina diagnostic branding and identity."

Is that correct?

A. Yes.

Q. So before, we were kind of trying to figure out whether there was a plan in place at the

time that this document was finalized with respect to branding of the products that were contemplated to be developed in this plan.

Do you remember discussing that?

A. Yes.

Q. A short-term need identified in the plan was to develop an Illumina diagnostic branding and identity; is that correct?

A. That's what it says, yes.

Q. Do you have any reason to think that that is inaccurate?

A. No.

Q. On the third bullet of the "Marketing" row, it says:

"Focus sessions on laboratory developed test applications."

Do you see that?

A. Yes.

Q. And that's identified as a short-term need for marketing in the plan?

A. Yes.

Q. Some of the products that are in this

plan, if they had been developed, would be used outside of laboratory developed test applications; right?

A. Products where we said we would achieve IVD clearance or approval would not be considered lab-developed tests.

Q. And in the short-term, was it contemplated in July 2009 that the focus of marketing would be on the LDT applications, since that's what could happen then?

A. This doesn't say "focus of marketing"; it says "focus sessions."

Q. In the "Marketing" row?

A. In the "Marketing" row? I'm not sure what that means by "sessions."

It -- it appears like a marketing tactic. It does not say "focus marketing," though.

Q. Could you refer to the bottom of page 33 of Exhibit 304 --

A. Uh-huh.

Q. -- with the heading "Risks."

A. Yes.

Q. The fourth bullet is:
"Failure to discover clinically relevant biomarkers."
Do you see that?
A. Yes.
Q. Illumina had planned to undertake research and development to partnerships to develop biomarkers in genetics for diagnostic purposes.
Is that accurate?
A. Can you restate that?
Q. I don't know.
You didn't have any biomarkers yet in July 2009. You planned to get some?
A. The cancer discovery section was about looking for biomarkers relevant to oncology.
And this bullet is about whether or not we would find them in that discovery effort.
Q. Because you can devote resources to that research and development and plan for a pipeline to come, but there's a risk that you just don't discover those biomarkers; right?
A. With that particular endeavor, there was a

risk that we might not find something.
Q. The sixth bullet says:
"Delays in QSR compliance."
Right?
A. Yes.
Q. That refers to the risk that either changing the design or manufacturing of existing products to be QSR compliant, or designing products and manufacturing them in a QSR compliant manner from scratch would take longer than anticipated.
Is that what that risk is about?
A. The -- the risk is about delays in establishing QSR in the manufacturing pipeline for the products listed in the document.
Q. Is there a reason that you wanted to restate that instead of saying "Yes" or "No"?
A. You said "from scratch." I don't know. I -- I didn't -- the way that you asked the question when you said "developing it from scratch."
The -- the risk was about changing the manufacturing process and how long it would take.
Q. I see.

Thank you.
And so the risk to the program and achieving revenue forecast that's identified on 33, that says "delays in QSR compliance," refers to the time that it may take to make changes to existing manufacturing techniques to bring them into QSR compliance?
A. Yes.
Q. The next bullet point down says that:
"A risk to the program and achieving the revenue forecast is skepticism by customer on ability for Illumina CLIA lab to support true clinical testing."
Do you see that?
A. Yes.
Q. Why would a customer have been skeptical in July of 2009 and going forward about Illumina's CLIA labs ability to support true clinical testing?
MR. HORNE: Lacks foundation.
THE WITNESS: In 2009 our CLIA service was

to do whole genome sequencing, and the clinical utility of whole genome sequencing was in the process of being established.
So by establishing that clinical utility, we would address the -- the skepticism by customers.
BY MR. HANKINSON:
Q. Some new work needed to be done to convince customers that the CLIA lab sequencing would be useful in true clinical testing?
A. The -- the clinical utility of the test needed to be established.
Q. And the person who might not feel that the utility had been established was the customer; is that correct?
A. Yes.
And I would say the customer, in this example, would be a physician.
Q. Any physician or a particular type or field of physician?
A. Well, that's somewhat -- somewhat circular.

The -- the intention of establishing ourselves as a CLIA lab to do whole genome sequencing is to help build the evidence of the clinical utility of whole genome sequencing.

And that clinical utility would be directed to a particular type of physician, so that use was in development.

Q. It's an example of Illumina driving adoption of a new technology as opposed to entering a market where the use was already -- the utility was already recognized by the customer?

A. That's correct.

MR. HANKINSON: Can we take like a couple minute break, and then, probably, I'm done.

MR. HORNE: Absolutely.

Let's go off the record.

DEPOSITION OFFICER: Off the record.

(Whereupon, a recess was held from 1:09 p.m. to 1:22 p.m.)

DEPOSITION OFFICER: Back on the record.

MR. HANKINSON: Ms. O'Grady, thank you very much. I don't have any further questions at

this time.

I understand that counsel for your company, Illumina, is going to ask one question, he says -- although sometimes that's accurate -- in what we call redirect.

I'm not aware at this time of the rules governing whether he's allowed to do that, so we're going to lodge an objection and reserve our rights to any relief related to that later, but go ahead and allow it to happen so that we've got the record if it's appropriate and needed.

THE WITNESS: Okay.

MR. HORNE: And for the record, the purpose of this redirect is to clarify testimony given today, to the extent that makes any difference going forward.

EXAMINATION

BY MR. HORNE:

Q. Ms. O'Grady, you were asked a question earlier in your deposition about genotyping, and I believe the question was whether genotyping relates

to inherited disease.

Do you remember that?

A. Yes.

Q. Is that all that genotyping relates to?

A. No.

Q. What else does genotyping relate to -- or could genotyping relate to?

MR. HANKINSON: Objection; three questions.

Go ahead.

THE WITNESS: Our genotyping products, or the way we refer to genotyping, is discriminating bases from each other to identify variants or answer questions.

And that has application in inherited disease; in oncology for somatic variant detection, or discriminating variants in a tumor.

And it also is applicable to distinguishing pathogens from each other in an infectious disease environment.

BY MR. HORNE:

Q. Is that all?

A. There may be other uses of genotyping that I didn't mention.

Q. Okay. No further questions.

MR. HANKINSON: Brief recross.

EXAMINATION

BY MR. HANKINSON:

Q. Would Illumina's customers in the diagnostics market understand the answer that you just gave?

A. I believe so.

MR. HANKINSON: That's all.

MR. HORNE: Done.

DEPOSITION OFFICER: Off the record.

(Whereupon, at the hour of 1:24 p.m., the proceedings were concluded.)

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STATE OF CALIFORNIA)
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DATED: This day 18th of December, 2014.

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TRACY M. FOX, CSR Number 10449
Certified Shorthand Reporter

Naomi O'Grady c/o
KNOBBE MARTENS
10100 Santa Monica Boulevard, 16th Floor
Los Angeles, California 90067

Case: Illumina, Inc. v. Meridian Bioscience, Inc.
Date of deposition: December 4, 2014
Deponent: Naomi O'Grady

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Deposition Date: December 4, 2014

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Witness Name: Naomi O'Grady
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EXHIBIT 7

Illumina Receives FDA 510(k) Clearance for Its BeadXpress Multiplex Analysis System

Provides Clinically Validated Platform for the Next Generation of Molecular Diagnostic Tests

SAN DIEGO – May 3, 2010 – (BUSINESSWIRE) – Illumina, Inc. (NASDAQ:ILMN) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) market clearance for the company's BeadXpress system for multiplex genetic analysis. According to the FDA's indications of use, the BeadXpress system – consisting of Illumina's BeadXpress Reader and VeraScan software – is an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing VeraCode holographic microbead technology.

"This approval represents a significant and exciting transitional step for Illumina into the diagnostics field, where the potential is great for molecular medicine to make a real difference in the way disease is detected and ultimately prevented and treated," said Jay Flatley, president and CEO. "It demonstrates Illumina's ability to meet stringent regulatory requirements in designing and manufacturing an FDA-cleared in-vitro diagnostic device. This will serve as an important foundation for our future plans in the diagnostics area. Ultimately, our goal is to become a leader in translational medicine, focusing on complex diseases that benefit from high performance analysis, including genotyping, copy number, gene expression, methylation and protein analysis."

Illumina introduced the BeadXpress system in 2007 with Research Use Only kits for custom genotyping, gene expression, methylation and protein analysis. Since then it has been adopted by research, agricultural, industrial and pharmaceutical institutions worldwide. Utilizing uniquely inscribed digital microbeads, VeraCode technology provides high-quality data, broad multiplexing capability and assay flexibility. Illumina submitted the system for FDA review in September 2009.

"510(k) clearance opens up a wide range of new possibilities for our many clinical research and commercial partners, who can now pursue diagnostic development on our proven, high-performance BeadXpress platform," said Gregory Heath, Ph.D., senior vice president and general manager, Diagnostics. One of those partners is EraGen Biosciences, Inc., which concluded a licensing agreement with Illumina in 2009 to transfer their assays onto the BeadXpress System. "This clearance is a significant step forward in progressing our partnership in the clinical marketplace," said Irene Hrusovsky, M.D., president and CEO of EraGen Biosciences.

For more information, please visit www.illumina.com.

About Illumina

Illumina (http://www.illumina.com) is the leading developer, manufacturer, and marketer of integrated systems for the analysis of genetic variation and biological function. Using our proprietary technologies, we provide a comprehensive line of products and services that currently serve the sequencing, genotyping, and gene expression markets, and we expect to enter the market for molecular diagnostics. Our customers include leading genomic research centers, pharmaceutical companies, academic institutions, clinical research organizations, and biotechnology companies. Our tools provide researchers

around the world with the performance, throughput, cost effectiveness, and flexibility necessary to perform the billions of genetic tests needed to extract valuable medical information from advances in genomics and proteomics. We believe this information will enable researchers to correlate genetic variation and biological function, which will enhance drug discovery and clinical research, allow diseases to be detected earlier, and permit better choices of drugs for individual patients.

Forward-Looking Statements

This release contains forward-looking statements that involve risks and uncertainties. Important factors that could cause actual results to differ materially from those in any forward-looking statements include challenges inherent in new product development and manufacturing and the other factors detailed in our filings with the Securities and Exchange Commission, including our most recent filings on Forms 10-K and 10-Q, or in information disclosed in public conference calls, the date and time of which are released beforehand. We undertake no obligation, and do not intend, to update any forward-looking statements after the date of this release.

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EXHIBIT 4

genomeweb

Illumina Unveils Strategy to Enter Molecular Diagnostics Market

January 21, 2009

Illumina Unveils Strategy to Enter Molecular Diagnostics Market

By Turna Ray

Illumina plans to enter the molecular diagnostics space by forging partnerships with customers, opening a new CLIA lab, and launching a research project to study cancer genomes, CEO Jay Flatley said during a recent presentation to investors.

Speaking at the JPMorgan Healthcare Conference in San Francisco last week, Flatley said the company will invest to improve existing sequencing technologies and develop new ones to enable it to play in the molecular diagnostics space, which he estimates to be worth $3 billion.

"We are really excited about what's happening in the sequencing market," Flatley said during his presentation. "We think over the next few years, it's going to be the most exciting segment in life sciences tools, so we continue to make major investments in this space."

As part of what Flatley called Illumina's "platform partnering" program, the company plans to work with customers to develop diagnostic applications using its existing BeadXpress genotyping platform and the sequencing technology it acquired last summer when it bought Avantome.

With the BeadXpress platform, Illumina has already begun partnerships to develop genotyping assays for blood typing, pharmacogenomics, and prenatal testing, Flatley said. Illumina hopes to garner clearance from the US Food and Drug Administration for the BeadXpress platform in the second half of the year.

Illumina has yet to commercialize the Avantome technology. Flatley did not update investors on the types of sequencing-based diagnostic tests Illumina plans to develop with the Avantome platform, or the partners Illumina is working with on this effort.

Additionally, Illumina plans to open its own CLIA-certified diagnostic laboratory, which will allow the company to introduce tests and testing services while waiting for the US Food and Drug Administration to clear test kits being developed under its partnering program.

He said the CLIA lab will also enable Illumina to offer services based on proprietary content from

its licensing and discovery programs, and to offer sequencing services for "traditional [genetic] targets" such as carrier testing for Rett syndrome; drug-resistance testing for HIV and Mycobacterium; mutation detection in the genes P53, KRAS, BRAF, EGFR; and HLA testing.

The company plans to apply for CLIA-certification during the first half of this year and hopes to start generating revenue from diagnostic services in the second half of 2009. An Illumina spokeswoman told *PGx Reporter* sister publication *In Sequence* this week that the company's primary interest for the CLIA lab is to provide sequencing services on its Genome Analyzer.

The last piece of Illumina's plan to enter the diagnostics space involves an internal discovery-research project to study ovarian and gastric cancer. To that end, the company plans this year to sequence approximately 50 cancer genomes and their controls, and to conduct whole-trascriptome and methylation-profiling analyses of these samples, Flatley said.

After validating the results in a larger number of samples, Illumina plans to implement diagnostic tests using these results on its array platform. Specifically, for ovarian cancer, Illumina aims to "identify very early markers for diagnosis" and to "begin to look at the genetics of therapy resistance, in particular resistance to platinum therapy," according to Flatley.

He said Illumina can embark on a project of this scale because "we can sequence so rapidly, and at such great cost points."

The decreasing cost of sequencing technologies has particularly impacted the nascent consumer genomics industry. Both 23andMe and Navigenics have said they plan to offer their customers whole-genome sequencing as the costs of this technology decrease.

Flatley told the JPMorgan conference that the molecular diagnostics market will grow from $3 billion to $5 billion by 2011, while the sequencing market will grow from $1.1 billion to $1.5 billion during that period. Illumina is betting that its sequencing know-how will enable it to win a slice of the broader molecular diagnostics space.

In this regard, Flatley said Illumina plans to launch several new products in the near term, including a sequencing add-on module, called Harmonia. The module works in concert with Illumina's iScan genotyping platform, set for launch in the second half of this year, and will be marketed to the company's genotyping customers who want to try sequencing technology.

Last week, as reported in *In Sequence*, Illumina announced it had made an $18 million investment into UK-based startup Oxford Nanopore Technologies. Oxford's nanopore sequencing technology "holds tremendous promise to be one of the first technologies to reach the sub-$1,000 genome and become the cheapest and fastest way to sequence DNA," Flatley said during his presentation (see *In Sequence* 1/13/2009)

— *Julia Karow, editor of* In Sequence, *contributed to this article.*

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EXHIBIT 15

Illumina CEO Jay Flatley on Diagnostics, the $1K Genome & China

Luke Timmerman 1/15/13 Follow @ldtimmerman

Illumina is the dominant player in the high-speed gene sequencing business, and has been for a number of years. That powerful position in a field that's vital to the future of healthcare has made it the object of intense scrutiny, and in some cases, scorn, from customers, competitors, and potential acquirers.

Last year, the big event came when the San Diego-based instrument maker (NASDAQ: **ILMN**) fought off a $6.7 billion **hostile takeover bid from Switzerland-based Roche**, saying in essence that it could be a lot more valuable on its own. Many of its actions since could be interpreted as the moves of a hunter, not a company that sees itself as prey.

After the dust settled last spring in the Roche takeover battle, Illumina bought a couple of diagnostics companies, **BlueGnome** and **Verinata Health**, to follow through on its stated plan to morph into a more diversified maker of research tools and genomic diagnostic tests. The company has been racing to fend off rivals in the sequencing business like Carlsbad, CA-based **Life Technologies** (NASDAQ: **LIFE**), and smaller players such as **U.K.-based Oxford Nanopore** that pose technological threats to its platform for DNA sequencing. Illumina has ruffled more than a few feathers in the industry with some aggressive moves, including **an unsuccessful bid to stop BGI-Shenzhen from acquiring** Mountain View, CA-based Complete Genomics (NASDAQ: **GNOM**).

I met with Illumina CEO Jay Flatley to discuss all of these issues and more during a wide-ranging interview last Tuesday (January 8th) at the JP Morgan Healthcare Conference in San Francisco. Here are excerpts of the conversation, edited for length and clarity.

Jay Flatley, CEO of Illumina

Xconomy: You have been one of the busiest newsmakers in the industry lately. You bought Verinata Health, then another company, **Moleculo**, a spinout from Stanford University. You pre-announced **fourth quarter revenues of $309 million** that

were higher than consensus expectations on Wall Street. You reportedly said no to another recent acquisition inquiry from Roche. What else is up your sleeve for this year?

Jay Flatley: We have a lot going on, we're busy fellows. We have a pretty rich pipeline of opportunities that come our way now, because of the size we are and the presence we have in the market. We get to look at lots of different companies. It's driven in part by the challenges in the life sciences venture capital industry. Some are getting out of the business. Sometimes small companies get to the first step in development, and they are looking for strategic partners, or for somebody to buy them out. So we get to look at a lot of things. We don't do that many. We do a handful of tuck-ins per year, and occasionally a big one like Verinata.

X: How has your strategy around acquisitions changed after the whole Roche thing ended last spring? Do you see yourselves increasingly as the acquirer, rather than the acquired?

JF: Our M&A strategy changed a bit a few years ago, and Roche didn't particularly influence any change. We used to be more opportunistic—if something came to us and looked interesting, we'd look at it. Now we're much more proactive. We have a full-time staff that does nothing but this, scouring the States and the world for good licensing opportunities, or good companies that we think we ought to own.

X: What kinds of things are you most interested in now? Diagnostic companies, or new technologies to build up the platform?

JF: It spans a wide range. We're clearly looking at diagnostics, we've been very public about that the past couple of years. We're looking for something to really enhance our penetration in diagnostics, more rapidly than we could organically. Verinata certainly does that. We've looked across the entire space. There frankly aren't that many high-quality assets that can move the needle for us, and we think Verinata can.

We're always looking for good technology pieces, and Moleculo is a great example. It's a company that's young and small, but they have a great technology that will help inch our product line forward in some interesting ways. We are always looking for interesting assay methods out there. Software is an area we have been looking.

X: Do you worry about how getting aggressive in M&A might backfire? There has been some commentary made about you guys moving to compete against Sequenom (NASDAQ: **SQNM**) in the prenatal genetic testing market. These guys, I believe, are your No. 1 customer.

JF: They are a very important customer to us. The goal here certainly isn't to compete directly with Sequenom. One of the things we've tried to make very clear—and we talked to them before we announced this—is that our goal is to make the whole field expand and continue to have them be a strong customer for us. There are couple components to this. One is that we think Verinata has the foundational IP in the field, and we think the field is being held back a little bit by IP overhang. There may be a way now that we can work that out. I'd like to see if that's possible.

We clearly have a partnering strategy to take this technology to the market. We'd love to partner this (Verinata Health's prenatal genetic test). Part of what we've done here is in recognition of the fact that in five years, this is going to be an IVD (in vitro diagnostic) market. People will want an FDA-approved test they can run in lots of labs. While the technology was split up, with assays being in other companies, and us having the platform, there was no really easy way to get an application through the

FDA. We'd love to work with all these companies. We want to help Sequenom, help Ariosa (Diagnostics) and further our business as well.

X: What other kinds of diagnostics are you looking to tuck in?

JF: We've been very active in the cancer field, but these are not things we think are going to be acquisitions. They are tools we put out on the market. For example, we put out a somatic cancer panel. It's to help accelerate CLIA (centralized clinical labs). They can add additional content on top of this. But it's to get these labs to begin to do cancer vs. normal tissue screening. It's not that likely we're going to have a material acquisition in cancer anytime soon. But we're continuing to watch the field. We have a lot of customers. It's a very big market with lots of indications. I don't think there's any risk of us competing with our customers in cancer.

X: What about technology acquisitions? Moleculo is one of those. They'll enable you to do more long-read DNA sequence lengths, right? Others, like PacBio, have tried to push ahead on that front to gain an advantage. What's your rationale for that acquisition?

JF: The great thing about the Moleculo technology is that in order to get long reads, you don't have to sacrifice throughput or cost. That's the problem with the other systems. You sacrifice accuracy, with, say, [Oxford] Nanopore's technology or PacBio. Here we get the accuracy of SBS (sequencing by synthesis) chemistry, plus the long reads. The incremental amount of (extra) sequencing you have to do is very small. It's about one extra lane on a HiSeq machine to get a full human genome.

It opens up about 10 percent of the next-generation sequencing market that we think really wants long reads. It's for areas like structural variations in cancer, or de novo sequencing—particularly in complex plant genomes. There are applications like meta-genomics, where you're sequencing a complex soup of things, when you're looking at a number of different organisms present, and you're trying to ask, is this organism present? Having a couple hundred base reads sometimes isn't enough to figure that out. Certainly there are some clinical applications, in being able to determine whether you're dealing with a mutation in a gene, or whether it's from the paternal or maternal strand, can make a big difference in the diagnosis.

Over time, this will be a standard part of what we do. There is some inherent improvement in accuracy when you move to long reads.

X: Are you really going to be able to get reads that go all the way up to 10,000 bases of DNA?

JF: Just the data they have already hits that. The chart I showed today, the maximum read length was 13,000, the average read length was 7-8,000 base range. We actually have an internal program where we can get up to 100,000 base reads. These are synthetic, so to be clear, these aren't actually using SBS chemistry to read 10,000 bases in a row. It's labeling the ends of short reads, and then reconstructing them afterwards. So we call it a synthetic long read. But the accuracy is astounding.

X: Why did you say no to Roche's overtures again?

JF: We said no to Roche at our annual meeting in April, and that's the last comment we made on Roche.

X: Yes, but they made some recent overture that was reported...

JF: There's been a bunch of stuff reported in the press, but we didn't comment on it.

X: So why remain an independent Illumina? Why does that make sense for the company and its shareholders?

JF: We're certainly not wedded to that notion. We've said that openly. This was a matter of having a fair price, and a price that we think puts an end to the upside our shareholders enjoy. To truncate that value at some fixed number requires a number that's materially bigger than any number we've seen. When you look at $51, we were trading at $55 just a few weeks ago. A $51 per share offer just wasn't in the ballpark.

X: When you look at the markets you can enter, how big do you think the opportunity is, and what kind of share price does that justify?

JF: The markets for sequencing are going to be enormous. Many, many, many billions of dollars when you look out 5-8 years from now. The cancer market will be enormous. The newborn screening market is going to be enormous. If you look just at NIPT (non-invasive prenatal genetic testing) alone, today there's a $1 billion of value just in doing amniocentesis. This is going to be much bigger than that, because it will be done by more women in the high-risk group who avoid amnio because of the risk to the fetus (potential miscarriages). And it will expand into low-risk pregnancies, because this is a test you can do with virtually zero risk. That market alone has multiple billions of potential.

X: And you think Verinata has the IP advantage in a four-way dispute (with Sequenom, Ariosa Diagnostics, and Natera) the other entrants?

JF: We think so. Nobody's certain about that until you get to the end of the process, but there's a chance we can make something work here with the other players.

X: Why did you guys oppose the Complete Genomics merger with BGI-Shenzhen (for $118 million)?

JF: Oppose is maybe...we asked that CFIUS (Committee on Foreign Investment in the United States) get involved, and they did. We think BGI owning it has national security implications, and we thought it was bad that they'd get it. To our surprise, CFIUS let it go through. Yesterday, the Federal Trade Commission approved it too, so we withdrew our bid today (Tuesday Jan. 8).

X: Why is it bad for national security?

JF: Because we think there's risk they could build very large databases, and get access to the genomes of lots of Americans. They could bring them back to China. There are lots of nefarious ways you could use the information. There are theoretical bad things you could do with those kind of databases if they aren't regulated by the law of the United States. So we were concerned about BGI's affiliation with the Chinese government. We'll have to see how it plays out.

X: Isn't BGI one of Illumina's biggest customers? They have bought a ton of your HiSeqs.

JF: Yes, they are a very significant customer of ours. We want to maintain a great relationship with them. But we're not sure it's in the U.S. national interest to sell the formula for Coke. It's different when people just buy Coke.

X: Has there been tension in the relationship with BGI since you took this action?

JF: Until this sorted out, in terms of who was going to make the Complete Genomics acquisition, we haven't had a lot of interaction with them. But I'm certain now that it looks like we know how it's going to go, we'll get re-engaged with them and have open discussions about how we can move the relationship forward.

X: How do you think you're doing vis-à-vis the competition? It's an extraordinarily competitive field, with Life Technologies, Complete Genomics, PacBio, Oxford Nanopore and others.

JF: I think we're doing well. We just pre-announced $309 million in revenue in the fourth quarter, which was a record quarter for us. We think we're continuing to add significant market share against our competitors. We take them seriously and think they are strong competitors.

X: Do you think Illumina still has the edge, technology-wise?

JF: Yes. We have a very rich pipeline of new products. We're fortunate enough now to be big enough that we can invest in a broad way to improve things like sample prep, and bioinformatics. It's not just for the sequencers. It's enabled us to introduce new products like Basespace, which we think is a very important cloud-based add-on to our sequencing ecosystem.

X: I want to come back for a bit to the diagnostics world for a minute. I've heard some rumblings this week about people being unhappy with Illumina moving into this area, and trying to take over the world. I've heard about some moves to jack up prices of reagents for diagnostics company customers. They seem threatened. Are you threatening a lot of your customers, who are aspiring molecular diagnostics companies?

JF: Not at all. We do think in the diagnostics market, the requirements those companies appropriately place on us, in terms of having different products, better lot tracking, keeping longer inventories, giving them advance notice of changes—it all requires us to build a different infrastructure inside the company, a parallel infrastructure. That's expensive for us. We're putting all those capabilities and systems and duplicate part numbers in place. As a result of that, we think premium pricing is justified for diagnostic kits.

X: So there was a recent price increase for diagnostic customers, compared with standard academic research labs?

JF: Pricing for our RUO (research use only) kit is different than for diagnostic customers. They are separate market segments. The diagnostic group does their pricing based on whatever the cost is of the infrastructure.

X: But was there a price increase recently?

JF: Don't think of it like that. It's not like it was some price one day and it changed. It wasn't an increase. But we're starting to have new products we put in the market that have different capability. They have different packaging, different lot tracking, different shelf life, different notification and supply agreements. They are priced appropriately.

X: So these customers have a different set of needs, and they are paying more?

JF: Exactly. And if they want to keep using our RUO reagents, they can continue to do that. We aren't forcing them to take those new products.

X: What worries you the most when you look at the business landscape?

JF: In 2012, (federal budget) sequestration was clearly the biggest worry we had. It caused a lot of uncertainty in the business, and we didn't know how customers would respond to it. We've come out of 2012 with much less impact than we might have anticipated. That's probably less of a worry for us now. Now, it's probably just

tracking what the competition is doing, and making sure we are in the market with products that as are competitive as we can make them.

X: What's the biggest problem your customers are facing, that you need to solve?

JF: It probably relates to interpretation of genomes. We've had great work done on the core sequencing engine, and made a lot of progress on sample prep. On the front end couple pieces of software, we've made lots of progress there, in terms of reducing file sizes and aligning genomes and call variants. Now the problems are moving into things like what the genome means, and what the variants mean. A lot of academic world is focused there, and we're trying to help. Particularly around cancer.

X: Did you actually hit the $1,000 genome threshold by the end of 2012? I know that both you and Life Technologies, if memory serves, said at this meeting (JP Morgan Healthcare Conference) last year that you'd be able to sequence an entire human genome in one day for $1,000.

JF: That's not quite accurate. What happened exactly a year ago at this meeting is that two companies announced they would have ability to sequence a complete human genome in a day. One company said they could do it for $1,000, and that was Life Technologies. We never put any pricing out in the market, but we said we could do the sequencing in a day. In February, we presented the first data on that. In the second quarter, we deployed the technology in our services operation. In the third quarter, we put it in the hands of customers. In the fourth quarter, we shipped it in volume. We delivered exactly on the program we promised.

X: So what does it cost now to do a whole genome, just the sequencing, on a HiSeq?

JF: It varies, depending on the volume of the customer. The discounts can vary, depending on what their usage rates are. If you look at the range of numbers, if you look at instrument depreciation and reagent costs, it varies from a couple thousand dollars up to $5,000. It depends also on what mode you run the instrument in, too. It's a bit more expensive to run the instrument in rapid mode than in high-throughput mode.

X: How do you stack up on cost with Life Technologies at this point?

JF: We're very competitive. Right now at least, they're not doing whole human genomes.

X: With the SOLiD or the Ion Torrent?

JF: The SOLiD isn't much of a factor in the market anymore. With Ion Torrent, to our knowledge, they aren't at the output levels people will use for human genomes.

X: It's more about targeted, regional sequencing, right?

JF: Yes.

X: Personally, this had to be a very intense year for you. How do you feel about what you're doing. Triumphant? Vindicated? Do you feel good about what you're doing?

JF: I've never been more optimistic about the company and the markets we're in. I feel very good about how the technology stacks up right now. We've got a great management team, and a great overall team. It's a lot of fun to do what we do. It was an intense year from a workload perspective. Particularly in that Roche (hostile takeover bid) window, there were three or four weeks when we did not much else.

But after that was over, we spent our time doing the blocking and tackling it takes to run a business and produce more innovation.

Luke Timmerman is the National Biotech Editor of Xconomy. E-mail him at ltimmerman@xconomy.com Follow @ldtimmerman

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Illumina, Inc. v. Meridian Bioscience, Inc.

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ILLUMINA Reg.No. 2632507 *Class 1* - chemicals, namely reagents for scientific or medical research use for analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing DNA, genotyping, gene expression profiling and high through-put screening. Class 42 - scientific and medical research, namely, analysis of cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing DNA, genotyping, gene expression profiling and high through-put screening.	**ILLUMIPRO-10** Ser.No. – 77/775316 *Class 10* - Diagnostic machine, namely, a stand alone closed heater and turbidity meter to be used for the amplification and detection of a closed tube molecular assay.
ILLUMINA Reg.No. 2756703 *Class 9* - Scientific equipment and instruments, namely scanners, hybridization stations and fluidics delivery and computer systems sold as a unit and cassettes containing molecular sensing optical fiber bundles for analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 Dalton, sequencing DNA, genotype, gene expression profiling and high through-put screening.	**ILLUMIGENE** Reg.No. – 3868081 *Class 5* - Diagnostic kits consisting of molecular assays for use in disease testing and treatment of gastrointestinal, viral, urinary, respiratory and infectious diseases.
ILLUMINADX Ser.No. 77/747038 *Class 9* - Clinical diagnostic instruments, namely, nucleic acid sequencers, imaging devices and analyzers for use in scientific, diagnostic and clinical research and for clinical diagnostic purposes; laboratory equipment, namely, fluid containers, fluid mixers, fluid control valves and temperature-controlled incubators for sample preparation, amplification, mixing, hybridization, incubation, and washing; automated laboratory apparatus and systems, namely, sample loaders and bar code readers; computer systems, namely, computer hardware, computer software, and data files for collecting, storing, analyzing and reporting biological information, and for sample tracking and managing projects, laboratory workflow and data, all the foregoing for use in the fields of scientific, diagnostic and clinical research and for clinical diagnostic purposes. *Class 42* - Clinical diagnostic services in preparing, amplifying, labeling, detecting, analyzing and sequencing nucleic acids and other biological molecules from human beings or animals	**ILLUMIGENE MOLECULAR SIMPLIFIED & design** Reg.No. – 3887164 *Class 5* - Diagnostic kits consisting of molecular assays for use in disease testing and treatment of gastrointestinal, viral, urinary, respiratory and infectious diseases.
ILLUMINADX Reg.No. 4053668 (parent to child, above)	

Illumina Marks	Meridian Marks
Class 5 - Clinical diagnostic reagents, reagent kits, and beads with attached biomolecules, comprised primarily of enzymes, oligonucleotides and other nucleic acids, natural and modified nucleotides, buffers, labels, and substrates, for clinical diagnostic purposes.	

Mark	Owner	Ser./Reg. No.	Filing Date	First Use Date
ILLUMINA	Illumina, Inc.	2471539	June 15, 2000	February 00, 1999
ILLUMINA	Illumina, Inc.	2632507	August 18, 2000	February 23, 2001 October 12, 2001
ILLUMINA	Illumina, Inc.	2756703	August 18, 2000	January 09, 2003
ILLUMIGENE	Meridian Bioscience, Inc.	3868081	November 17, 2008	July 21, 2010
ILLUMIGENE MOLECULAR SIMPLIFIED & design	Meridian Bioscience, Inc.	3887164	April 1, 2009	July 21, 2010
ILLUMINADX	Illumina, Inc.	77/747038	May 28, 2009 (parent)	n/a
ILLUMINADX	Illumina, Inc.	4053668	May 28, 2009 (child)	March 19, 2010
ILLUMIPRO	Meridian Bioscience, Inc.	77/768176	June 25, 2009	n/a [July 21, 2010]
ILLUMIPRO-10	Meridian Bioscience, Inc.	77/775316	July 07, 2009	n/a [July 21, 2010]

Hankinson, Thomas F.

From: Brian.Horne [Brian.Horne@knobbe.com]
Sent: Monday, May 04, 2015 2:59 PM
To: Hankinson, Thomas F.
Cc: Hurst, J. Michael; ILLINC.266M
Subject: Illumina v. Meridian - O'Grady Rebuttal Declaration

Tom:

In reviewing her rebuttal declaration, Ms. O'Grady realized that she had misinterpreted Illumina's records as they relate to a statement she made in Paragraph 31 about Dr. Young. More specifically, her statement that Dr. Young "has purchased an Illumina Bead Array reader" is incorrect. Instead, Illumina was in communication with Dr. Young's laboratory between 2009-10 about potentially purchasing a Bead Array reader. During that time, Illumina provided access to its "KaryStudo" software, which is a software package that performs cytogenetic analysis from bead array products. Illumina provided the license at no charge for the lab to evaluate the software and reporting solution for consideration of purchasing a Bead Array Reader for cytogenetic analysis. That evaluation did not convert to a sale.

Brian

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

ILLUMINA, INC.,	Opposition No. 91194218 (parent) Ser. No. 77/768176
Opposer/Petitioner,	
-v-	Opposition No. 91194219 Ser. No. 77/775316
MERIDIAN BIOSCIENCE, INC.,	Cancellation No. 92053479 Reg. No. 3887164
Applicant/Registrant.	
	Cancellation No. 92053482 Reg. No. 3868081

DECLARATION OF MICHAEL PATRICK IN SUPPORT OF APPLICANT / REGISTRANT'S MEMORANDUM IN OPPOSITION TO OPPOSER / PETITIONER'S MOTION FOR SUMMARY JUDGMENT

I, Michael Patrick, hereby state and declare as follows:

1. My name is Michael Patrick, I am over eighteen (18) years of age, and I have personal knowledge of the facts stated in this Declaration.

2. I graduated from the University of Alabama at Birmingham in 1995 with a major in Industrial Distribution.

3. I am employed by Meridian Bioscience, Inc. ("Meridian") as Senior Director of Sales and Marketing. I have been with Meridian for the past five years, starting as a Product Manager and working my way up to my current position.

4. In connection with my duties and responsibilities for Meridian, I supervise and direct Meridian's marketing efforts for clinical diagnostic products. I am also directly involved in selling Meridian's clinical diagnostic products to customers, and I have considerable experience meeting and corresponding with Meridian's customers for clinical diagnostic products. I have gained substantial personal knowledge of our customers' specialties, organizational structures, and needs.

5. I have worked in the marketing discipline of the medical industry for more than eleven (11) years. Prior to working at Meridian, I worked in marketing for Wright Medical Technology, Inc., a manufacturer of orthopedic products. Prior to that, I worked in marketing for Esoterix, Inc., which sold clinical diagnostics products related to leukemia and lymphoma. Prior to that, I worked in marketing at Polymedco, a supplier of clinical diagnostic test kits and devices related to chemistry, hematology and various types of cancer.

6. During my employment with Esoterix, Polymedco, and Meridian, I devoted extensive time to learning about the relevant customer base for clinical diagnostics products, meeting with customers, selling products to them, and negotiating agreements with them. Through my years of personal experience in marketing clinical diagnostic products and services, I have become well acquainted with the suppliers, customers and markets for such products.

The Differing Consumers of Meridian's Products versus Illumina's, From 2008 To Today

7. Meridian has been in the clinical diagnostics field since its founding in 1977. Meridian has been a leader in the field of clinical diagnostics since it pioneered its first *C. Difficile* test in 1992.

8. Within the broader category of infectious disease, Meridian's clinical diagnostic products are focused in the microbiology space. Meridian's "molecular diagnostic" products test for and identify the microbial invader; Meridian's products do not focus on or have any relationship with the genetics of the human patient.

9. The consumers of clinical diagnostic products in the microbiology space are typically the Clinical Directors of clinical diagnostic laboratories, who acquire such products often at the request of personnel in the laboratories' "Infectious Disease" or "Microbiology" departments or with the purpose to supply them to such departments. Since 1977, Meridian has sold diagnostic products to clinical diagnostic laboratories to assist them in diagnosing infectious diseases – specifically, microbiological infectious diseases.

10. The people within the clinical diagnostic laboratories who use Meridian's clinical diagnostic products are typically situated in a "Microbiology" or "Infectious Disease" group or department. The products used in this context must be FDA-approved for "*in vitro*" use, often referred to as "IVD" products. The ultimate decision-maker for buying Meridian's clinical diagnostic products – including Meridian's ILLUMIGENE products – is typically the head of a clinical diagnostic laboratory, i.e. the Clinical Director (sometimes with input or required consent or "sign-off" from financial personnel such as a Purchasing department, Materials Management department, or CFO or Director of Finance for the laboratory)

11. The Clinical Director is typically one of two (2) "director-type" positions within the larger laboratory setting of a hospital or reference lab environment. The other director at this level is the "Research Director." Meridian does not market or sell to, and rarely if ever has any interaction with, the Research Director in a hospital or reference lab setting. As a result, to say that Meridian markets and sells its products to "hospital labs" or "reference labs" is an oversimplification of how the relevant consumer market is structured. In reality, there are two separate and distinct "touch-points" within any "hospital lab" or "reference lab;" the research lab and the clinical diagnostic lab. Meridian's marketing and sales focus is only to one of those two distinct touch-points – the clinical diagnostic lab.

12. While hospitals and reference labs generally do purchase microbiological clinical diagnostic products, those products are purchased specifically for and by the microbiology departments within the clinical diagnostic labs of such hospitals and reference labs. Put another way, the consumers within a hospital or laboratory who interact with the relevant products in this case, select products, and drive the purchase of products within each of those markets are very different and very specific.

13. The relevant consumers in the clinical diagnostic laboratories of hospital labs and reference labs have been familiar with Meridian's infectious disease clinical diagnostic products

for more than twenty-five (25) years, and certainly well prior to 2008. Meridian has spent a great deal of money advertising and selling its clinical diagnostic products specifically to such consumers. In 2009, Meridian spent almost $350,000 in marketing diagnostic products in the United States, with approximately $250,000 of that expenditure dedicated to promoting ILLUMIGENE products. The marketing and promotion for ILLUMIGENE's initial launch cost approximately $100,000, which included both advertising and promotional funds. In 2012, Meridian has spent about $15,000 per month in advertising ILLUMIGENE products in the United States, and Meridian spends an additional $75,000 annually in trade show promotion of Meridian. Given Meridian's marketing and sales strategy and the strict separation of the clinical and research disciplines within any given hospital lab or reference lab, the relevant consumers on the research side of such labs – i.e. the consumers of Illumina's products - probably have very little if any familiarity with Meridian. Conversely, Meridian's relevant consumers on the clinical diagnostics side of such labs probably have very little if any familiarity with Illumina.

14. Illumina is not and has not been a competitor of Meridian and does not offer goods to the same consumers as Meridian. Because of the line of business Illumina is in, Illumina's consumers, where they otherwise overlap in the larger hospital lab and reference lab channel of trade, are those on the research side of such labs. Outside of this channel, Illumina also markets to and serves dedicated research institutions where human genomes are sequenced on a massive scale for, among other things, drug development purposes. Meridian has no involvement in this space whatsoever.

15. In five (5) years of marketing Meridian's products, I have encountered many competitors and other companies who offer clinical diagnostic products and services, but I have never once heard of Illumina operating in the clinical diagnostic space, never once heard a customer refer to Illumina or its products, and never once encountered Illumina as a competitor.

Specifically, Meridian's main competitors in the clinical diagnostic space are BD/GeneOhm, Prodesse, Alere and Cepheid.

16. In 2008, Illumina did not offer any clinical diagnostic products whatsoever and did not offer any products or services related to infectious diseases or microbiology. Rather, Illumina was a company that offered human genetic sequencing services and supplied equipment and components for companies and laboratories to construct their own "assays" (scientific tests). Those products and services are directed toward and used by an entirely different category of consumers from consumers of clinical diagnostic products.

17. The consumers of Illumina's products have been distinct from the consumers of Meridian's products since Illumina's inception, and were certainly distinct in 2008 and 2009. Today, the relevant consumers of Meridian's and Illumina's products remain distinct notwithstanding Illumina's recent addition of new products.

18. Since its inception, and certainly in the 2008-2009 time frame, Illumina's market for its human genetic services, components, and equipment for assays included research laboratories, *not* clinical diagnostic laboratories. These research laboratories would purchase Illumina's human genetics services by sending away samples to be analyzed, and/or would buy components and equipment from Illumina to construct in-house assays. None of Illumina's products at the time were FDA-approved, IVD products. Rather, all of Illumina's products were approved for "Research Use Only," often referred to as "RUO" products. RUO products may not be used in clinical diagnostic laboratories to diagnose patients. Illumina's market also includes academic laboratories, government research entities such as the CDC and NIH, and large pharmaceutical companies who do substantial research; none of these entities has a clinical laboratory component or uses clinical diagnostic products of the type that Meridian markets.

19. It is inaccurate for Illumina to broadly assert that its consumers were or are part of the "diagnostics" market. The only connection to "diagnostics" that would be possible in this

context exists in very few laboratories, and does not involve any overlap between the *consumers* of clinical diagnostic products and the *consumers* of Illumina's products. In a few research laboratories, researchers create their *own, in-house* diagnostic assays. They may use Illumina's products, along with components from many other suppliers, to *build* these assays. But those researchers and the people working with them are not buying "ready-made" clinical diagnostic products such as Meridian's – they are buying components and then *building* in-house diagnostic assays themselves. Asserting that Illumina's components and equipment compete with Meridian's clinical diagnostic test kits based on this logic would be much like saying a bolt manufacturer competes with an automobile manufacturer because bolts are used to build cars.

20. And just as a consumer would not expect a bolt manufacturer to begin making cars, the personnel working in research laboratories who used Illumina's services and products since Illumina's inception, and certainly in 2008 and 2009, would not have expected Illumina to begin selling "ready-made" IVD diagnostic products. Personnel within clinical diagnostic laboratories in 2008 and 2009 would never have even heard of Illumina at all because Illumina *made no products for such personnel to use or purchase.*

21. Illumina's purchase of Epicentre Technologies Corporation, the maker of "DisplaceAce" is only a further example of this dynamic, i.e., the difference between the consumers of Meridian's products and the consumers of Illumina's products. DisplaceAce is a component – a bolt for the car – not a test or kit that can be used to determine whether a particular patient is afflicted with a particular infectious disease. Someone trying to diagnose the presence of an infectious disease in a clinical diagnostic laboratory cannot use DisplaceAce by itself for this purpose, nor would such person be aware whether DisplaceAce was being used as a component within a kit. And Illumina is flat wrong in claiming that ILLUMIGENE cannot be sold without DisplaceAce. When Illumina refused to sell Meridian DisplaceAce unless Meridian

abandoned the marks at issue in this proceeding, Meridian set to work at identifying a replacement enzyme for its ILLUMIGENE product. Meridian identified and validated an alternate supplier for the ILLUMIGENE products without any interruption to the availability of product to the market. Meridian now uses a different component in its products that it has determined, pursuant to FDA guidelines, to be substantially equivalent, and Meridian is allowed to use that replacement component under the relevant FDA regulations.

22. In November 2008, Meridian applied to register its ILLUMIGENE mark for diagnostic kits – FDA-approved "ready-made" IVD assays to diagnose infectious diseases in Clinical Diagnostic Laboratories. In April 2009, Meridian applied to register its ILLUMIGENE MOLECULAR SIMPLIFIED & design mark for the same products directed to the same market. At the time of Meridian's filings, consumers in the clinical diagnostic laboratory would not have had any awareness of Illumina or its products because Illumina did not offer any products they could use; Illumina had no IVD products in its product portfolio, but rather only RUO products for use by consumers working in research laboratories.

23. Even today, the consumers of Meridian's clinical diagnostic products and the consumers of Illumina's products are not the same. From its website, Illumina's product line still appears to consist of human genetic services and components and equipment for assays. As discussed above, consumers of such services and products are research laboratories, not clinical diagnostic laboratories. It is true that Illumina received FDA approval on April 28, 2010 for the "Illumina VeraCode(R) Genotyping Test for Factor V and Factor II," but Illumina's website does not appear to market that product, and I have not encountered it in my interactions with consumers in clinical diagnostic laboratories or in my attendance at tradeshows in the industry. Moreover, I saw Illumina's display at the recent American Society of Microbiology trade show on June 17-19 in San Francisco, and it did not include any marketing of IVD products.

24. Even if Illumina is given the benefit of the doubt about having an IVD product in the marketplace with its "Illumina VeraCode® Genotyping Test for Factor V and Factor II" ("VeraCode® Genotyping Test"), the fact remains that the consumers of the VeraCode® Genotyping Test are very different from the consumers of Meridian's infectious disease diagnostic products. The VeraCode® Genotyping Test for Factor V and Factor II tests *human genes* for mutations, using human blood samples, in an effort to identify the genetic markers for a blood disorder called thrombophilia. Meridian's molecular diagnostic products attempt to identify microbial pathogens, not particular sequences of human DNA.

25. The personnel who would perform tests using Illumina's VeraCode® Genotyping Test are in the clinical diagnostic laboratories' "Hematology" or "Oncology" groups or departments. Such groups or departments are wholly separate from the "Infectious Disease" or "Microbiology" departments or groups who are the consumers of Meridian's clinical diagnostic products. The work and tools of the two kinds of clinicians do *not* overlap.

The High Level Of Sophistication And Attention Of Meridian's and Illumina's Consumers

26. Although they are distinct groups of people, everyone involved in purchasing and using either Meridian's clinical diagnostic products or Illumina's services and products has an extremely high level of education and sophistication.

27. The user of a Meridian clinical diagnostic product is an educated and highly trained person within an "Infectious Disease" or "Microbiology" department or group in a Clinical Diagnostic Laboratory. He or she would usually have a bachelor's degree in a scientific field and training as a Medical Technologist. The user of Illumina's new VeraCode® Genotyping Test, if that product is indeed on the market, would also be educated and highly trained. He or she would usually have a bachelor's degree in a scientific field and training in molecular research. The needs of the consumers of these products would drive the purchase of such products by the clinical diagnostic laboratory. Both of these types of consumers pay close

attention to the product they are selecting and using. The consumers' ability to use the products at issue are restricted by FDA regulations pertaining to the intended uses of the products, and the consumers also must take great care because they are diagnosing medical conditions of patients.

28. The decision-maker in setting up a pricing contract with Meridian for purchasing Meridian's clinical diagnostic products, including ILLUMIGENE products, is typically a Clinical Director, the head of a clinical laboratory. The people in that position typically have even more education and credentials, usually including a Master's degree or even a Ph.D. They typically have a great deal of experience in clinical laboratories and sophisticated knowledge of the industry. Clinical Directors pay close attention to the pricing contracts entered into by their laboratories and the products they make available to their personnel through those contracts.

29. Further, it typically requires multiple meetings and/or calls between Meridian and its customers to enter into a contract for Meridian's clinical diagnostic products. Meridian and the relevant consumer will engage in significant negotiation over products, volumes, and prices. At all times, Meridian's customers are fully aware of what types of products Meridian can offer and what types it does not offer, as well as the names of those products.

30. The consumers of Illumina's human genetics services, and Illumina's components and equipment for assays, are researchers in research laboratories, academic laboratories, government research entities, or large pharmaceutical companies. Such personnel usually have a bachelor's degree in a scientific field and training in molecular and genetic research, and often have doctorate-level scientific degrees. They are highly trained scientists and laboratory technologists who pay close attention to the equipment, components and services that they use, in part because their results must be precise, verifiable and reproducible. They typically disclose the equipment and components that they use when they write scientific papers that include their methodologies.

The Substantial Price Differences Between Meridian's Products And Illumina's Products

31. Even if the same consumer encountered both Meridian's clinical diagnostic products (such as the ILLUMIGENE molecular diagnostic kits and the ILLUMIPRO and ILLUMIPRO-10 machines that read them) and Illumina's products (such as Illumina's VeraCode® Tests and the BeadXPress equipment that reads them), they would not be likely to confuse the source of the products, in part because of the extreme price difference between them.

32. Meridian's ILLUMIGENE molecular diagnostic products are marketed for between $1,250 and $3,000 per kit of 50 tests ($25 to $60 per test). Meridian's ILLUMIPRO and ILLUMIPRO-10 machines ***are included at no additional charge with the purchase of the initial kit***.

33. On information and belief, Illumina's BeadXPress readers, used to interpret the VeraCode® tests, are priced at about $95,000. This price does not include the cost of the components used in the actual test itself. Clearly a purchaser would be very likely to note the dramatically different order of expense between the two companies' products, even apart from the major, obvious differences in what the products are and what they do, as discussed above.

Prefixes In Product Names In the Medical Products Field

34. I understand that Illumina has argued that the prefix "ILLUMI" is somehow more noticeable or more entitled to weight than the suffix that follows it in ILLUMIGENE, ILLUMIPRO, and ILLUMIPRO-10. Based on my extensive experience in marketing in the field of medical products, I disagree with Illumina's position.

35. In the medical field, the prefixes of product names are often the same or very similar across different companies who compete with each other. For example, "Immuno" is an extremely common prefix used in the product names of many different companies, such as the Quest Immunocap, the Allere ImmunoComb, and the Meridian ImmunoCard. Because of this

pattern of concentrations on the same prefixes, consumers of medical products do not merely focus on the prefixes of words more so than, or at the expense of, the suffixes and/or the entirety of the word, or give the prefixes special weight or attention. If anything, given the consequences of using the wrong product by casually focusing on only part of a product name, consumers of medical products are attuned to the need to take in and consider the entirety of the product names.

36. An especially clear example of the dynamic described above can actually be found in another product name prefix that *Illumina itself* began using years after Meridian began using it. In 2006, Meridian applied to register the marks TRU RSV, TRU FLU, TRU EBV-M, and TRU EBV-G. The first uses of these marks were in 2006 and 2007 and they were registered in 2008. All of these registrations are in International Class 5, and recite "diagnostic tests" or "diagnostic test kits."

37. Subsequently, in the summer of 2010, Illumina submitted two applications to register the mark TRUSEQ, one with a claimed first use date of November 22, 2010. Illumina's TRUSEQ mark was successfully registered in International Classes 1, 9 and 42 for "reagents and reagent kits" for use in "diagnostic and clinical research"; "product development" within the "fields of scientific, diagnostic and clinical research"; and "scientific instruments" within the "fields of scientific, diagnostic and clinical research."

38. It is not surprising to me that Illumina did not view the "TRU-" prefix shared by its' and Meridian's marks as particularly problematic for both entities to be using or that its TRU- mark was too close to Meridian's TRU- marks based on Meridian's prior registration and use of several marks with this same prefix. Not only were the products different, but Illumina's mark had a different suffix, rendering its TRUSEQ sufficiently different from Meridian's TRU RSV, TRU FLU, TRU EBV-M, and TRU EBV-G.

39. Illumina's apparent position in applying for registration of the TRUSEQ mark, notwithstanding Meridian's use and registration of several TRU- marks, makes sense. Its apparent reversal of its position in the current dispute does not make sense. These TRU- marks cover the same types of goods and services that are at issue in this proceeding. Illumina's own efforts in selecting, applying for, using, and registering its TRUSEQ mark directly contradict the position it is trying to assert in this proceeding. Consumers of medical and medical research products are careful and sophisticated, and they do not give undue weight to just the beginnings of product names, or ignore the endings.

40. I am not aware of any instances of actual confusion between Illumina's TRUSEQ mark and any of Meridian's TRU-formative marks, nor would I expect there to be any confusion.

There Is No Actual Confusion Between Meridian's Trademarks And Illumina.

41. After extensive marketing of Meridian's ILLUMIGENE clinical diagnostic products and the ILLUMIPRO and ILLUMIPRO-10 readers over the course of multiple years, there have been no reported incidents of confusion between these products and Illumina or its products.

42. Meridian first used the ILLUMIGENE name in connection with clinical trials in December 2008. Meridian has promoted ILLUMIGENE under that name since then, at all times including trade shows, individual meetings and customer presentations.

43. Since obtaining FDA approval and launching ILLUMIGENE products in July of 2010, Meridian has promoted them through trade shows, advertisements in trade magazines, promotion on Merdian's website, individual meetings, brochures, and customer presentations. Meridian has sold ILLUMIGENE products to more than 700 different accounts in the United States. Beyond those who have actually purchased ILLUMIGENE products, over 4000 potential consumers have been exposed to the ILLUMIGENE and ILLUMIPRO products through our marketing efforts. I estimate that Meridian representatives have met face-to-face with about 50% to 60% of accounts in the marketplace regarding ILLUMIGENE products, and that

Meridian's ILLUMIGENE advertising and promotion has reached almost 100% of the possible accounts in the marketplace, particularly since ILLUMIGENE is advertised in trade publications that reach virtually every clinical laboratory. With all of this marketing and sales activity, there have still been absolutely no accounts of purchasers or others confusing the source of ILLUMIGENE as being Illumina, nor confusing Meridian as being the source of any Illumina products.

44. In my position, I would hear about any reported confusion from a consumer or from someone responding to our marketing. If any of Meridian's marketing or sales personnel heard about such confusion, they would report it up to me. I would also expect to hear about any such confusion from distributors with whom we work.

Attendance At Broad-Based Trade Shows In This Industry Does Not Mean There Is Any Overlap In Consumers.

45. I understand that Illumina has argued that simply because it has attended some of the same trade shows as Meridian, the consumers for both Illumina's and Meridian's products are somehow the same. However, in the medical industry, attendance at broad-based trade shows does not mean, in and of itself, that all the companies at the shows are competitors or even sell products to the same consumers.

46. For example, the American Association for Clinical Chemistry Annual Meeting is a broadly-focused trade show where the vast majority of products and services on display, including such things as blood analyzers and gas analyzers, have nothing to do with the clinical diagnostics field. Further, many products on display are designated for Research Use Only ("RUO" products).

47. Similarly, the Association for Molecular Pathology trade show, although it is in the molecular pathology field generally, includes many companies who offer human genetic and polymorphism products and services which are not similar to Meridian's clinical diagnostic products and which do not have the same users. The same is true of the Clinical Lab Expo and

the Deutsche Bank Annual Health Care conferences: a wide array of products and services are presented at those conferences to a wide variety of professionals and potential consumers, and simply attending them does not mean that companies are marketing to the same consumers or are competitive with one another.

48. In short, Meridian's clinical diagnostic products are marketed and sold to different consumers that Illumina's products and services, and mere attendance at some of the same trade shows does not change that.

Pursuant to 37 C.F.R. § 2.20, the undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting therefrom, declares that all statements made of my own knowledge are true; and all statements made on information and belief are believed to be true.

Executed on June 29th, 2012.

Michael Patrick

ILLINC.266M

TRADEMARK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc., Opposer, v. Meridian Bioscience, Inc., Applicant.	Opposition No.: 91194218

DECLARATION OF GREGORY F. HEATH

I, Gregory F. Heath, Ph.D., declare as follows:

1. I have personal knowledge of the matters set forth herein and if called upon to testify, I could and would competently testify thereto.

2. I am a Senior Vice President of Illumina, Inc. and, from March 2008 through December 2013, I have been the General Manager of Illumina's Diagnostics Business Unit. In my current role with the company, as Senior Vice President of In Vitro Diagnostic (IVD) Development I am responsible for developing In Vitro Diagnostic products. I am also familiar with Illumina's use of the marks ILLUMINA®, ILLUMINADX®, ILLUMINOTES™, and ILLUMICODE™.

3. I have a B.S. in psychology from Illinois State University, an M.A. in experimental psychology from Hollins College, a Ph.D. in experimental psychology from Virginia Commonwealth University, and I completed my post-doctoral work in behavioral pharmacology at Michigan State University. I have published more than 25 articles and abstracts in science and business. I have more than 25 years of experience in the diagnostics field, including launching the first FDA-approved array for diagnostic use while employed at Roche Molecular

Systems and the first FDA-approved next generation sequencing product while at Illumina.

4. I was previously employed at Roche Molecular Systems, where I held a number of senior executive positions including Head of Clinical Genomics, Senior Vice President of Global Product Marketing, Senior Vice President of Global Marketing and Business Development, and most recently, Senior Vice President of Global Business. In my last role at Roche Molecular Systems, I was responsible for new product development and global marketing activities for the infectious disease, blood screening, genetics, and oncology portfolios. I was also responsible for the PCR (polymerase chain reaction) licensing, industrial business, and business development programs.

5. From 2000 to 2003, I was head of the Business Development and Licensing for the Diagnostics Division of F. Hoffman La Roche in Basel, Switzerland. There I led the strategic planning, business development, and licensing activities of the molecular diagnostics, centralized diagnostics, applied science, near patient testing, and diabetes care business areas. Prior to this, I held numerous roles in marketing and strategic planning with Roche Diagnostics' U.S. affiliate.

6. Illumina is a global company that develops, manufactures, and markets genetic analysis tools and integrated systems for the analysis of genetic variation and function, and provides services related to the same. More specifically, Illumina develops and sells innovative array and sequencing-based solutions for DNA and RNA analysis, which serve as tools for disease research and diagnosis, drug development, and for the development of molecular tests in the clinic. Illumina products and services serve life-sciences research, applied markets, and the molecular diagnostics market.

7. In April 2005, Illumina acquired VeraCode® technology through its acquisition of CyVera Corporation with the intention of using the technology in products for the molecular diagnostics market, which is part of the clinical diagnostic market. VeraCode® technology is an array-based technology that utilizes microscopic glass beads embedded with a digital

holographic element. VeraCode® beads are provided in a liquid suspension and are used in combination with an assay and reader to determine whether particular DNA sequences are present in a sample. For example, an assay, such as Illumina's GoldenGate® genotyping assay, is used to process a DNA sample to attach specific portions of the DNA to the VeraCode® beads. Illumina's BeadXpress® reader is then used to analyze the DNA samples attached to VeraCode® beads to determine whether specific, known DNA sequences are present in the sample DNA. Attached hereto as Exhibit 4 is a news article announcing Illumina's acquisition of CyVera. The VeraCode® technology formed the basis of Illumina's BeadXpress® diagnostic platform.

8. At the time I came to Illumina in 2008, Illumina was putting even more focus on the development of products and services for the molecular diagnostic market with the creation of a Diagnostics Business Unit. Attached hereto as Exhibit 101 is a true and correct copy of an Illumina press release dated January 4, 2008, announcing Illumina's corporate reorganization. In particular, the Diagnostics Business Unit was tasked with developing diagnostic content for the BeadXpress® system and, eventually, for Illumina's sequencing products. In March 2008, I was appointed to serve as the General Manager of Illumina's Diagnostics Business Unit. Attached hereto as Exhibit 102 is a true and correct copy of an Illumina press release dated March 17, 2008, announcing my appointment.

9. Since its formation in 2008, the Diagnostics Business Unit has become a major focus of Illumina. For example, in 2010, I hired Emily Winn-Deen as Vice President of Diagnostics Business Development. Attached hereto as Exhibit 103 is a press release announcing Ms. Winn-Deen's appointment at Illumina. Ms. Winn-Deen joined Illumina after working for more than 20 years in the life sciences and diagnostics fields. Ms. Winn-Deen has been responsible for overseeing a number of key development projects in diagnostics, including, for example, cancer diagnostics.

10. In 2011, Illumina partnered with Siemens Healthcare to develop an assay to

detect HIV. In fact, Illumina built a Biosafety Level 2 (BSL-2) lab for the Research and Development group at this time to be able to handle blood samples received through Illumina's work with Siemens. A BSL-2 lab is a special lab designed to contain biological agents in an enclosed facility. In the United States, the Centers for Disease Control and Prevention specify the required levels. A level 2 facility is required for work involving agents of moderate potential hazard and requires that laboratory personnel receive specific training in handling pathogenic agents and be directed by scientists with advanced training. Companies build these types of labs, and Illumina did build its lab, to be able to work with infectious diseases.

11. In 2011, Illumina appointed Dr. Daniel Grosu as Vice President and Chief Medical Officer to further build Illumina's diagnostic capabilities. Attached hereto as Exhibit 16 is a press release dated October 31, 2011, announcing Dr. Grosu's appointment. Prior to joining Illumina, Dr. Grosu worked in diagnostics development at Ortho-Clinical Diagnostics, Bayer Healthcare Pharmaceuticals, and Siemens Medical Solutions.

12. Since joining Illumina, Dr. Grosu has been instrumental in establishing a medical affairs team, which is responsible for engaging in peer-to-peer dialog with physicians about how to use sequencing and array technology in practice. Dr. Grosu has also been responsible for heading up and building a clinical development team, which has enabled Illumina to perform clinical trials with more expertise. For example, the clinical development team includes field managers who travel to clinical trial sites to assemble the locations and train the personnel who conduct Illumina's FDA clinical trials.

13. Beginning in 2006, Illumina had a formal development program to seek regulatory approval for its BeadXpress® system utilizing VeraCode® technology for in-vitro diagnostic use. In March 2009, Illumina shipped BeadXpress® devices to three clinical sites in the United States to begin the required clinical trials. As was the case with all of Illumina's BeadXpress® readers, those products were labeled with the ILLUMINA® mark. Attached hereto as Exhibit 104 is a true and correct copy of the Clinical Trial Report section of Illumina's

510(k) submission for the VeraCode® Genotyping Test for Factor V and Factor II.

14. In September 2009, Illumina formally submitted its BeadXpress® system and VeraCode® Genotyping Test to the FDA for 510(k) market clearance. On April 28, 2010, the FDA granted 510(k) market clearance for Illumina's BeadXpress® system for multiplex genetic analysis. According to the FDA's indications of use, the BeadXpress® system is an in-vitro diagnostic device intended for the simultaneous detection of multiple analytes in a DNA sample utilizing Illumina's VeraCode® holographic microbead technology. On April 28, 2010, the FDA also granted a separate 510(k) market clearance for Illumina's VeraCode® Genotyping Test for Factor V (Leiden) and Factor II (Prothrombin). These tests are used to identify Factor V and Factor II mutations, caused by an inherited blood clotting disorder known as thrombophilia, which increases the patient's risk for venous thrombosis. True and correct copies of press releases, articles, and presentations discussing Illumina's successful efforts to obtain regulatory approval for products designed for diagnostics are attached hereto as Exhibit 105. Attached hereto as Exhibit 36 are website printouts from the FDA 510(k) premarket notification database regarding Illumina's BeadXpress® system and VeraCode® Genotyping Test for Factor V and Factor II. Attached hereto as Exhibit 106 is a true and correct copy of a BeadXpress® System brochure.

15. Due to my aforementioned experience, I am very familiar with the time and costs involved in obtaining market clearance by the FDA for products used for human in-vitro diagnostic use. Prior to the submission of any product to the FDA for market approval, a company must complete extensive clinical trials, the results of which can take years to complete and compile into meaningful data. As a result, life sciences companies typically spend five years or more for internal development and clinical testing prior to submitting diagnostic products to the FDA. Depending upon the results of clinical trials and the satisfaction of other FDA requirements, FDA approval typically takes an additional nine months to two years before a product (with no known similar product that has already been cleared by the FDA) is cleared

for commercial market use.

16. In 2009, Illumina launched its Cancer Discovery Initiative to validate genes associated with ovarian cancer and gastric cancer using its sequencing platform. The goal of the project was to use sequencing to identify novel biomarkers to determine genes associated with these cancers. Cancer diagnostics could then be developed based on the identification of these biomarkers. For example, a patient's DNA sample could be sequenced and the results analyzed to determine whether that patient has any particular mutations associated with a particular type of cancer. This facilitates early disease detection and helps to predict a patient's likely response to therapy or relapse. Attached hereto as Exhibit 107 is a true and correct copy of a slide presentation Ms. Winn-Deen prepared in 2010 regarding Illumina's approach to cancer discovery and diagnostics development. In 2011, Illumina added colorectal cancer as a third cancer type to the ongoing project. Attached hereto as Exhibit 14 is a true and correct copy of a news article dated January 18, 2011, discussing Illumina's Cancer Discovery Initiative. Attached hereto as Exhibit 108 is a true and correct copy of an Illumina brochure dated March 25, 2011, titled "Cancer Genomics." Attached hereto as Exhibit 109 is a true and correct copy of an Illumina brochure dated March 25, 2011, titled "The Illumina® Cancer Discovery Initiative."

17. During the first half of 2009, Illumina completed its Clinical Services Laboratory and received CLIA certification. Illumina's achievement in obtaining CLIA certification for its diagnostic services lab was heavily promoted to its customers, the molecular diagnostics industry, and the general public. True and correct copies of press releases issued by Illumina, articles, advertisements, and brochures relating to Illumina's efforts in the diagnostics field are attached hereto as Exhibit 110.

18. "CLIA" refers to the Clinical Laboratory Improvement Amendments of 1988, which are federal regulatory standards for clinical laboratory testing. In the United States, any facility that performs laboratory testing on human-derived specimens for the purpose of providing information for diagnosis, prevention, or treatment of disease or impairment, or for

health assessments must be CLIA-certified. Because of the regulatory requirements that must be met, the CLIA certification process typically takes 3-6 months to complete. Indeed, Illumina began the project for its CLIA-certified diagnostics services lab in Q3 2008. Attached hereto as Exhibits 11 and 12 are news announcements dated November 18, 2008, and January 21, 2009, announcing Illumina's plan to open a CLIA-certified lab.

19. Illumina's diagnostic services lab has offered physician-ordered individual whole-genome sequencing services for diagnostic purposes. Illumina's whole-genome sequencing is an example of a laboratory developed test ("LDT"). A LDT is a type of in-vitro diagnostic test that is designed, manufactured, and used within a single lab. High-complexity CLIA-certified labs, such as Illumina's Clinical Services Lab, are allowed to develop LDTs and deliver results for these LDTs to physicians. For example, Illumina's whole-genome sequencing services are frequently used by pediatric geneticists to diagnose rare childhood diseases and by oncologists for cancer molecular profiling. A second LDT offered by Illumina's subsidiary, which brands its products and services with the ILLUMINA® mark, is non-invasive pre-natal testing through a CLIA-certified lab that Illumina acquired in 2013 through the acquisition of a company called Verinata Health. Illumina's non-invasive pre-natal testing is used by obstetricians and gynecologists to screen for aneuploidies, conditions resulting in one or more extra or missing chromosomes such as trisomy 21, which is commonly referred to as Down syndrome.

20. Illumina is continually developing the next generation of molecular tests, systems, and services that will facilitate earlier diagnosis, selection of appropriate therapies, and monitoring of disease progression. Illumina's technologies enable sophisticated analysis of pathogens and subtle changes in patients' genes and chromosomes, allowing clinical laboratories and physicians to personalize disease management for improved healthcare. In recent years, Illumina has received FDA clearance on a number of its products, and has sought approval on a number of new products as well.

21. For example, at least as early as August 2011, Illumina announced its plan to

submit its MiSeq® platform to the FDA for 510(k) market clearance approval for diagnostic applications. This information has been disseminated to Illumina's customers, to the molecular diagnostics industry, and to the general public. Attached hereto as Exhibit 15 is a true and correct copy of an announcement dated August 3, 2011, announcing Illumina's intent to seek FDA approval for the MiSeq® platform.

22. The availability of Next-Generation Sequencing ("NGS") technology at a lower price, along with the more focused applications of the MiSeq®, has led many clinical customers to purchase this sequencer.

23. On December 20, 2012, Illumina submitted its MiSeqDx® platform for FDA approval. Attached hereto as Exhibit 111 is a true and correct copy of Illumina's 510(k) Premarket Notification Letter regarding its MiSeqDx® platform sent to the FDA on December 20, 2012. Attached hereto as Exhibit 112 is a true and correct copy of the letter Illumina received from the FDA confirming that on December 26, 2012, the FDA received Illumina's 510(k) Premarket Notification submission for its MiSeqDx® platform.

24. On December 21, 2012, Illumina submitted its MiSeqDx® Cystic Fibrosis System for FDA 510(k) review. Attached hereto as Exhibit 113 is a true and correct copy of Illumina's 510(k) Premarket Notification Letter regarding its MiSeqDx® Cystic Fibrosis System sent to the FDA on December 21, 2012. Attached hereto as Exhibit 114 is a true and correct copy of the email Illumina received from the FDA confirming that on December 26, 2012, the FDA received Illumina's 510(k) Premarket Notification submission for its MiSeqDx® Cystic Fibrosis System.

25. On November 19, 2013, Illumina received FDA clearance for its MiSeqDx® platform and MiSeqDx® Cystic Fibrosis System. Attached hereto as Exhibit 39 is a true and correct copy of an FDA News Release announcing its approval of the Illumina MiSeqDx® for use with Illumina's Cystic Fibrosis Assays and universal kit for open use. Attached hereto as Exhibit 115 is an Illumina press release dated November 19, 2013, announcing the FDA approval of Illumina's MiSeqDx® for use with its Cystic Fibrosis assays and universal kit for

open use. FDA clearance of the MiSeqDx® with universal kit for open use allowed Illumina to promote this kit to others—including clinical diagnostic labs—to develop their own diagnostic tests.

26. Illumina has sought FDA clearance for multiple other diagnostic products as well. For example, on February 21, 2013, Illumina submitted its InfiniumDx™ CytoSNP-12 Assay for FDA review. The InfiniumDx™ CytoSNP-12 was used with Illumina's BeadArray™ technology to diagnose chromosomal anomalies associated with developmental delay and mental retardation. BeadArray™ technology is an array-based technology, similar to BeadXpress®. The InfiniumDx™ CytoSNP-12 assay was used to process DNA samples and attach specific portions of the DNA to an array. The array would then be inserted into a Hiscan® reader, which would determine whether specific, known sequences were present in the sample. Attached hereto as Exhibit 116 is a true and correct copy of Illumina's 510(k) Premarket Notification Letter regarding its InfiniumDx™ CytoSNP-12 Assay sent to the FDA on February 21, 2013. Attached hereto as Exhibit 117 is a true and correct copy of the letter Illumina received from the FDA confirming that on February 22, 2013, the FDA received Illumina's 510(k) Premarket Notification submission for its InfiniumDx™ CytoSNP-12 Assay.

27. By March 2013, Illumina began discussions with the FDA to submit its Prenatal In-Vitro Diagnostic Assay to the FDA for premarket approval. Attached hereto as Exhibit 118 is a true and correct copy of Illumina's Pre-Submission Information Letter regarding its Prenatal IVD Assay sent to the FDA on March 15, 2013. Attached hereto as Exhibit 119 is a true and correct copy of the letter Illumina received from the FDA confirming that on March 18, 2013, the FDA received Illumina's Pre-Submission for its Prenatal IVD Assay.

28. In the life sciences industry, the research and diagnostics markets are inextricably linked. Illumina now serves both markets as do many other companies such as Roche, GE Diagnostics/Healthcare and Bayer. True and correct copies of examples of companies selling both research and diagnostics products are attached hereto as Exhibit 120.

Although the documents in this exhibit were printed in 2012, many of the companies began serving both markets much earlier. For example, Roche has been in both the research and diagnostics markets for many years. More specifically, Roche acquired a company called Boehringer Mannheim in the 1990's, which had both diagnostics and life sciences businesses for decades. In addition, Roche collaborated with a company called Affymetrix to develop the first FDA-cleared array. The AmpliChip® array, which was cleared when I was at Roche in 2005, tests for the presence of two genes known to play a major role in the metabolism of many prescription drugs. In late 2012, Roche even attempted to acquire Illumina. Roche was particularly interested in Illumina's NGS technology and its application to diagnostics.

29. Indeed, it is common for a company to produce and sell goods for research use only (RUO) in addition and prior to selling diagnostic products. Unless a company begins by licensing or purchasing an approved technology from another company who has already conducted years of research on said technology, it is a natural progression to start using a technology for research, developing and refining said technology, and then eventually putting said technology into diagnostic use.

30. Both Illumina and Meridian Bioscience, Inc. advertise their products and services in the same trade magazines and promote their products and services to the same set of consumers and at the same trade shows. True and correct copies of advertisements and trade show exhibitor lists are attached hereto as Exhibit 121.

31. For example, Illumina markets its products and services to hospitals, clinical reference labs, clinical diagnostic labs, physicians, genomic research centers, academic institutions, government laboratories, and clinical research organizations, as well as pharmaceutical, biotechnology, agrigenomics, and consumer genomics companies. Meridian similarly markets its products and technologies to hospitals, reference laboratories, physician offices, research centers, veterinary testing centers, diagnostics manufacturers, and biotechnology companies. Attached hereto as Exhibit 55 is a true and correct copy of a

MedCity News Q&A with Meridian CEO Jack Kraeutler dated February 1, 2010, discussing Meridian's expansion into molecular testing.

32. I am familiar with Illumina's customers and potential customers for molecular diagnostic tests, systems, and services, as well as how those customers order such products and services. The customers for our molecular diagnostic products and services typically include lab managers, molecular supervisors, purchasing department personnel, physicians (including infectious disease doctors and pathologists), medical geneticists, hospital administrators, genetic counselors, lab directors and lab technicians, but also include others interested in cancer, genetics, infectious diseases, and transplantations. Our molecular diagnostic tests, systems, and services can be ordered by our customers through all standard channels, including via direct telephone, via our web site, via email, at trade shows, through sales representatives, and internationally through distributors.

33. While Illumina does offer customized products and services, a number of its products, including its diagnostics products, are "off the shelf" goods and standard services with set purchase prices. For example, Illumina's array and sequencing instruments are off the shelf goods that can be purchased at set prices. Moreover, it is not necessary for the purchaser to have a pre-negotiated purchasing contract with Illumina to order many of its products including its diagnostic products. In fact, Illumina has an e-commerce site on its homepage, through which customers can order Illumina products. Illumina has operated this e-commerce site since 2004.

34. Illumina has used its ILLUMINADX® mark in connection with its products and services that target the diagnostics market. Representative examples of the use of the ILLUMINADX® mark are attached hereto as Exhibit 122. More recently, Illumina has rebranded its products and now markets almost all of its products and services with the ILLUMINA® mark. However, Illumina's VeraCode® Universal Bead sets are still sold with the ILLUMINADX® mark.

35. I am familiar with Clinica, IVD Technology, GEN, and CAP Today, which are

publications cited in Illumina's declarations and notice of reliance.

36. Clinica is an online publisher that serves professionals in the clinical lab space such as lab directors, laboratory-based physicians, and lab technicians.

37. IVD Technology is an online publisher that serves professionals in the clinical lab space such as lab directors, laboratory-based physicians, and lab technicians, as well industry professionals such as original equipment manufacturers and developers of in vitro diagnostic products.

38. GEN is an online and print publisher that serves medical directors, laboratory directors, and industry professionals.

39. CAP Today is an online and print publisher that primarily serves laboratory professionals including lab directors and lab technicians.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting therefrom, declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Executed this 7th day of November, 2014 at San Diego, California

Gregory F. Heath, Ph.D.

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CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing OPPOSER'S DECLARATION OF GREGORY F. HEATH upon Applicant's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on November 7, 2014, addressed as follows:

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